

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ROANOKE DIVISION**

<p>SHIRE LLC,</p> <p style="padding-left: 40px;">a Kentucky limited liability company,</p> <p style="padding-left: 80px;">Plaintiff,</p> <p style="padding-left: 40px;">v.</p> <p>TRAVIS C. MICKLE, PH.D.,</p> <p style="padding-left: 40px;">a citizen of Iowa,</p> <p>and</p> <p>KEMPHARM, INC.,</p> <p style="padding-left: 40px;">an Iowa corporation,</p> <p style="padding-left: 80px;">Defendants.</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>Civil Action No. 7:10-CV-00434</p> <p>JURY TRIAL DEMANDED</p>
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DEFENDANT TRAVIS C. MICKLE, PH.D.'S ANSWER AND COUNTERCLAIMS

Defendant Travis C. Mickle, Ph.D. ("Defendant" or "Dr. Mickle") hereby respectfully submits this Answer and Counterclaims in response to the Complaint of Plaintiff Shire LLC ("Plaintiff" or "Shire").

STATEMENT OF THE CASE

1. Shire brings this action against Mickle and KemPharm for equitable relief and monetary damages as a result of Mickle's breach of an employment agreement ("the Employment Agreement") (attached as Exhibit 1), five patent assignments ("the Assignment Agreements") (attached as Exhibits 2-6), a settlement document ("the Settlement Agreement") (attached as Exhibit 7) and for KemPharm's tortious interference with the Employment Agreement and Assignment Agreements.

ANSWER:

Defendant Dr. Mickle admits that Shire filed a Complaint against Defendants Dr. Mickle

and KemPharm, Inc. ("KemPharm") seeking equitable relief and monetary damages and alleging that Dr. Mickle breached an employment agreement ("the Employment Agreement"), which was attached to the Complaint as Exhibit 1, five patent assignments ("the Assignment Agreements"), which were attached to the Complaint as Exhibits 2-6, a settlement document ("the Settlement Agreement"), which was attached to the Complaint as Exhibit 7, and for KemPharm's alleged tortious interference with the Employment Agreement and Assignment Agreements. Defendant Dr. Mickle denies that Plaintiff has any cause of action against Defendants Dr. Mickle and KemPharm and denies the remaining allegations of this paragraph.

PARTIES

2. Shire is a Kentucky limited liability company with its principal place of business in Florence, Kentucky. Shire is the successor-in-interest to New River Pharmaceuticals Inc. ("NRP"), a former Virginia corporation headquartered in Radford, Virginia. At certain times relevant to this litigation, NRP was known as or traded as Lotus Biochemical Corporation.

ANSWER:

On information and belief, Defendant admits that Shire is a Kentucky limited liability company with a place of business in Florence, Kentucky. Defendant also admits that New River Pharmaceuticals, Inc. ("NRP") had an office believed to be headquartered in Radford, Virginia. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies the same.

3. Mickle is a citizen of Iowa. Mickle is the President and Chief Scientific Officer of KemPharm.

ANSWER:

Defendant admits that Dr. Mickle is a citizen of Iowa and is President of KemPharm. Defendant denies the remaining allegations in this paragraph.

4. KemPharm is an Iowa corporation with its principal place of business in Iowa City, Iowa. KemPharm also has a facility in Blacksburg, Virginia.

ANSWER:

Defendant admits that KemPharm is an Iowa corporation and that it leases a facility in Blacksburg, Virginia. Defendant denies the remaining allegations in this paragraph.

JURISDICTION AND VENUE

5. This Court has original jurisdiction over this matter pursuant to 28 U.S.C. § 1332 in that the matter in controversy is between citizens of different states and exceeds the sum or value of \$75,000, exclusive of interest and costs.

ANSWER:

Defendant admits that Plaintiff invokes the jurisdiction of this Court pursuant to 28 U.S.C. § 1332 and that the matter in controversy is between citizens of different states and exceeds the sum or value of \$75,000, exclusive of interest and costs. Defendant denies the remaining allegations in this paragraph.

6. The Court may exercise personal jurisdiction over the defendant Mickle pursuant to Va. Code Ann. § 8.01-328.1. Mickle has also expressly consented to this Court's jurisdiction in his Employment Agreement, which stipulated that "the exclusive jurisdiction for any lawsuit brought to enforce any right[s] or obligations arising under this agreement shall be. . . the United States District Court for the Western District of Virginia." Ex. 1, Employment Agreement ¶ 13(a). Mickle reaffirmed his consent to jurisdiction in this Court when he entered into the Settlement Agreement. Ex. 7, Settlement Agreement ¶ 5

ANSWER:

Defendant admits that Plaintiff invokes the jurisdiction of this Court pursuant to Va. Code Ann. § 8.01-328.1, and that Defendant executed an Employment Agreement attached as Ex. 1 to the Complaint and a Settlement Agreement attached as Ex. 7 to the Complaint, which documents speak for themselves. Defendant denies the remaining allegations in this paragraph.

7. This Court may exercise personal jurisdiction over the defendant KemPharm pursuant to Va. Code Ann. § 8.01-328.1.

ANSWER:

Paragraph 7 of Plaintiff's complaint does not require a response by Defendant Dr. Mickle. To the extent that Paragraph 7 is deemed to require a response, Defendant denies the same.

8. Venue in this district is proper pursuant to 28 U.S.C. § 1391.

ANSWER:

Denied.

FACTS

A. New River Pharmaceuticals and the CarrierwaveTM Technology

9. NRP was a specialty pharmaceutical company founded in 1996 and headquartered in Radford, Virginia. NRP conducted the majority of its research and development activities at its facility in Blacksburg, Virginia.

ANSWER:

On information and belief, Defendant admits that NRP was a pharmaceutical company headquartered in Radford, Virginia, which conducted the majority of its research and development activities at its research and development facility in Blacksburg, Virginia. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies the same.

10. The NRP business model focused on developing novel, safe pharmaceuticals that were improved versions of widely-prescribed drugs in large and growing markets. Key aspects of this business strategy included a product focus that would take advantage of the shortened development and regulatory approval pathways for drug products that also enjoy intellectual property protection. NRP implemented this "prodrug" business strategy through CarrierwaveTM technology, a proprietary process developed by NRP.

ANSWER:

Defendant admits that NRP worked on developing select pharmaceuticals intended to be improved versions of certain prescribed drugs in large markets. Defendant further answers that this allegation is vague, and Defendant denies any implication that the above accurately describes NRP's actual business or "business model" or that NRP's technology is or was the same or similar to the very different technology which Defendant later independently developed in connection with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph involving the specific meaning ascribed by Plaintiff to the phrase, CarrierwaveTM technology, and therefore denies the same. Defendant denies the remaining allegations in this paragraph.

11. The term CarrierwaveTM refers to the process in which prodrugs are produced by the chemical attachment of a ligand, such as amino acid or polypeptide, to an active pharmaceutical ingredient ("API") in order to improve the API's pharmacological, pharmaceutical or pharmacokinetic properties. Upon administration to a patient, the API is released. This CarrierwaveTM technology served as the platform on which NRP built its research and development activities.

ANSWER:

Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph including the specific meaning ascribed by Plaintiff to the term CarrierwaveTM and therefore denies the allegations of this paragraph. Defendant further denies any implication that the above accurately describes NRP's actual business or "business model" or that NRP's technology is or was the same or similar to the very different technology which Defendant later independently developed with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP.

12. Applying Carrierwave™, NRP's research and development efforts focused on developing prodrugs of amphetamine and opioids (e.g., oxycodone and hydrocodone) designed to provide overdose protection, abuse resistance and less potential for addiction while delivering efficacy comparable to the APIs on which they were based.

ANSWER:

Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph including the specific meaning ascribed by Plaintiff to the term Carrierwave™ and therefore denies the allegations of this paragraph. Defendant further denies any implication that the above accurately describes NRP's actual business or "business model" or that NRP's technology is or was the same or similar to the very different technology which Defendant later independently developed in connection with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP.

13. Through its extensive research and development efforts spanning over five years, NRP developed several products utilizing the Carrierwave™ technology. During this time, NRP came to focus its research on prodrugs consisting of an API conjugated to amino acids.

ANSWER:

Defendant admits that NRP came to focus its research on certain prodrugs consisting of certain APIs conjugated to only certain standard amino acids through specific processes. Defendant denies any implication that NRP came to focus its research on prodrugs consisting of an API conjugated to non-standard amino acids and pcesses for same. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph concerning the meaning ascribed by Plaintiff to the term, Carrierwave™, and therefore denies the remaining allegations of this paragraph. Defendant further denies any implication that the above accurately describes NRP's actual business or "business model" or that NRP's technology is or was the same or similar to the very different technology which

Defendant later independently developed with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP.

14. NRP had a number of products in its development pipeline by October 2005, in particular the following are lead compounds that incorporated the APIs of amphetamine, hydrocodone and oxycodone:
 - a. NRP104 is a prodrug of amphetamine used to treat ADHD symptoms. NRP104 became known as Vyvanse[®] and was approved by the FDA in early 2007. NRP104 consists of an amphetamine conjugated to an amino acid.
 - b. NRP290 is a prodrug of hydrocodone, an opioid widely used in combination with other non-opioid analgesics to treat acute pain. NRP290 consists of hydrocodone conjugated to amino acids.
 - c. NRP369 is a prodrug of oxycodone, an opioid used to treat chronic pain. NRP369 consists of oxycodone conjugated to amino acids.

ANSWER:

Defendant admits that NRP had at least three potential products in its development pipeline by October 2005, including a lead compound, the prodrug NRP104, namely, lisdexamfetamine dimesylate, which consists of a particular mesylate salt of d-amphetamine conjugated to the standard essential amino acid, l-lysine, for treatment of ADHD symptoms, which later became known as Vyvanse and was approved by the FDA in 2007. Defendant further admits that another potential lead compound was prodrug NRP290, which is purportedly modified hydrocodone, which consists of hydrocodone, a semi-synthetic opioid analgesic, used in combination with other non-opioid analgesics to treat acute pain, conjugated to one or more standard amino acids. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore denies the same.

15. As part of its business plan, NRP entered into an agreement with Shire Pharmaceuticals Group, plc on January 31, 2005, to assist with certain aspects of the development of NRP104.

ANSWER:

On information and belief, Defendant admits that NRP had some arrangement with Shire Pharmaceuticals Group, plc. Defendant further states that he lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore denies the same.

16. As a result of the progression of the relationship between Shire and NRP, Shire announced on February 20, 2007, that it would acquire NRP in a \$2.6 billion cash transaction. This transaction closed later that year. At that time, Shire became NRP's successor-in-interest.

ANSWER:

Defendant admits that Shire announced that it would or had acquired NRP for \$2.6 billion. Defendant lacks sufficient knowledge or information to admit or deny the allegations in this paragraph, and therefore denies the same.

B. Mickle Joins NRP and Is Introduced to Carrierwave™

17. On March 5, 2001, NRP hired Mickle as a Senior Scientist, and Mickle entered into the Employment Agreement. See Ex. 1.

ANSWER:

Defendant admits that on March 5, 2001, Lotus Biochemical Corporation ("Lotus") hired Dr. Mickle as a Senior Scientist and on or about March 6, 2001 Lotus and Dr. Mickle executed the referenced Employment Agreement. Defendant denies the remaining allegations in this paragraph.

18. The relevant provisions of Mickle's Employment Agreement are reproduced below:

4. Ownership of Materials.

All documents, diagrams, formulations, records, customer lists, Discoveries (as defined in Section 7 hereof) . . . which in any way relate to the Company's past, present or potential business and which were prepared or received by Employee in the course of Employee's employment are the exclusive property of the Company. Employee specifically acknowledges that Employee has no ownership interests or rights of any kind in or to such materials even if Employee developed such materials.

* * *

6. Confidential Information

Employee acknowledges that some business information may not qualify as a "trade secret," but it is still uniquely valuable and important asset of the Company, and Employee holds such information in trust for the Company's sole benefit. *Employee agrees that at all times while employed by the Employer and thereafter, Employee will not use for Employee's own personal benefit or for the benefit of others or disclose to any other person, corporation, or other entity for any reason any of the Confidential Information, without the prior written consent of the Board of Directors of the Company.* "Confidential Information" as used in this Agreement will include: this Agreement and all provisions hereof, all information acquired by Employee from the Company, its suppliers, advertisers, customers, or others during Employee's employment which relates to the Company's past, present or potential business, such as programs, files, personnel information, Discoveries (as defined in Section 7 hereof) to the extent not disclosed to the public by the Company. . . the Company's past, present or future research and development, business plans or strategies, business activities or affairs, marketing plans, product development plans, production methods and plans, software and financial information.

7. Discoveries

All Discoveries are the exclusive property of the Company, and Employee will promptly and fully disclose them to the Company. As used herein, the term "*Discoveries*" means *all discoveries, inventions, improvements, processes, ideas and names in any form, whether or not patentable or copyrightable (including records thereof), as well as all Intellectual Property (as defined herein), which relate to or are useful to the Company's business which Employee alone or with others may invent, discover, make or conceive whether the Company's facilities are used or not.* As used herein, the term "Intellectual Property" means all current and future worldwide patents and other patent

rights, inventions, copyrights, trade secrets, trademarks, know-how, utility models and other intangible proprietary rights, including, without limitation, all applications and registrations with respect thereto These obligations will survive termination of employment.

* * *

11. Enforcement.

Employee understands and agrees that the Company will suffer irreparable harm if Employee breaches any of Employee's obligations under this Agreement, and that monetary damages will be inadequate to compensate the Company for any such violation. Accordingly, Employee agrees that in any event Employee violates or threatens to violate any of the provisions of this Agreement, the Company, in addition to all the **remedies** which it may have, will be entitled to temporary, preliminary, and permanent injunctions to prevent or to restrain any such actual or threatened violation by Employee, or by any or all of the employees, partners, employers, agents, or other persons, directly or indirectly acting for, or on behalf of, or with Employee. Employee consents to the issuance of such injunctions as being a reasonable measure to protect Company's rights.

Ex. 1, Employment Agreement (emphasis added).

ANSWER:

Defendant states that the provisions shown above are incomplete and further states that the terms of the Employment Agreement between Dr. Mickle and Lotus Biochemical Corporation are set forth therein and speak for themselves. Defendant denies that the Employment Agreement contains any of the bold emphases or ellipses that appear above. Defendant further denies that the above provisions are relevant or support Shire's claims. Defendant denies the remaining allegations in this paragraph.

19. The Senior Scientist position at NRP was Mickle's first full-time job with a pharmaceutical company after graduation.

ANSWER:

Defendant admits that his first full-time job with a pharmaceutical company was after

receiving his Ph.D. Defendant denies the remaining allegations in this paragraph.

20. Mickle commenced his work with NRP on or about March 5, 2001, after which time NRP provided Mickle with significant training, drug development know-how and access to NRP's proprietary information, including without limitation its past, current and planned research and development activities. In particular, he was introduced to NRP's platform technology, CarrierwaveTM.

ANSWER:

Defendant denies that he commenced his work with NRP on or about March 5, 2001, but states that he began his employment on that date with Lotus Biochemical Corporation. Defendant further states that the term "significant" is vague and ambiguous in the context of this allegation. Defendant denies the allegation that NRP provided Dr. Mickle with significant training and drug development know-how. Defendant further denies any implication that he had unlimited access to NRP's proprietary information and drug development know-how. Defendant further states that he lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph concerning the meaning ascribed by Plaintiff to the term, CarrierwaveTM, and therefore denies the allegations pertaining to the same. Defendant further denies any implication that the above accurately describes NRP's actual business or "business model" or that NRP's technology is or was the same or similar to the very different technology which Defendant later independently developed with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP. Defendant denies the remaining allegations in this paragraph.

21. Thereafter, Mickle was promoted to Director of Chemistry, where he directed and supervised the research activities of several research scientists and associates. The research focused on the coupling of three different APIs (amphetamine, hydrocodone and oxycodone) to one or more natural, unnatural, non-standard, or synthetic amino acids (*i.e.*, ligands).

ANSWER:

Defendant admits that after a promotion at NRP, he generally directed and supervised some of the research activities of some research scientists and associates directed to particular medicinal chemistry in conjunction with particular prodrug work focused on the attachment of d-amphetamine, hydrocodone, oxycodone and/or certain salts thereof to certain of one or more natural standard amino acids. Defendant further denies any implication that the above accurately describes NRP's actual business or "business model" or that NRP's technology is or was the same or similar to the very different technology which Defendant later independently developed with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP. Defendant denies the remaining allegations of this paragraph.

22. In January 2003, Mickle became the Director of Drug Discovery and Chemical Development ("Director"). The Director's role was critical to NRP's efforts to patent and commercialize its prodrug discoveries.

ANSWER:

Defendant admits that he became involved in what may be characterized as a Director's role, but denies that his role involved the commercialization of prodrug discoveries. Defendant lacks sufficient knowledge or information to admit or deny that his role was critical to NRP's efforts to patent and commercialize its prodrug discoveries, and therefore denies these allegations.

23. In June 2003, Mickle discovered the potential for the wide-ranging application of non-standard amino acids conjugated to amphetamine and narcotics (e.g., hydrocodone and oxycodone) in the prevention of abuse. Mickle and those that reported to him devoted considerable time and energy to developing, testing and analyzing the viability of amino acid conjugates as part of the drug discovery work performed at NRP.

ANSWER:

Defendant denies that in June 2003 Dr. Mickle discovered the potential for the wide-ranging application of non-standard amino acids conjugated to d-amphetamine and narcotics (e.g., hydrocodone and oxycodone) and their derivatives in the prevention of abuse. Defendant admits that he and some of those that reported to him in June 2003 devoted considerable time and energy to developing, testing and analyzing the viability of d-amphetamine, hydrocodone, oxycodone and/or certain salts thereof conjugated with certain of one or more natural standard amino acids at NRP. Defendant states that some of such testing and viability was conducted by NRP employees that did not report to him. Defendant denies the allegations and implications of the second sentence of this paragraph as to non-standard amino acids. Defendant further denies any implication that the above accurately describes NRP's actual business or "business model" or that NRP's technology is or was or was the same or similar to the very different technology which Defendant later independently developed with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP. Defendant denies the remaining allegations of this paragraph.

24. As Director, Mickle supervised all drug discovery efforts including medicinal chemistry, analytical development and biological testing, and also supervised commercial process transfer, process optimization, Current Good Manufacturing Practices, synthesis and the manufacturing of several drugs.

ANSWER:

Defendant admits that at NRP he supervised some discovery efforts as to medicinal chemistry, process optimization as to development (but not to commercialization), and synthesis and manufacturing as to research and development (but not to commercialization) concerning

certain natural standard amino acids. Defendant incorporates his answer to paragraph 14, above.

Defendant denies the remaining allegations in this paragraph.

25. Throughout his employment, NRP disclosed and made available to Mickle its business plans and strategies, its methods of operation, its know-how, its drug discovery efforts, its commercialization processes and its approach to and results from its various research and development efforts. During this same time period, Mickle contributed certain information, ideas, discoveries, inventions, processes and methods of operation directed to improving and enhancing NRP's drug development efforts, which were targeted to the conjugation of amphetamine, hydrocodone and oxycodone to one or more natural, unnatural, non-standard, or synthetic amino acids.

ANSWER:

Defendant admits that at some time during his employment, NRP disclosed and made available to Dr. Mickle some limited information regarding its drug know-how, drug discovery efforts, potential commercialization processes and its approach to and results from its various research and development efforts, but denies that all such information was disclosed or made available to him. Defendant denies the remaining allegations of the first sentence of this paragraph. With respect to the second sentence of this paragraph, Defendant states that allegation terms such as “ideas” and “discoveries” are not defined in the Complaint, yet are purportedly defined in the Mickle-Lotus Employment Agreement (D. E. 1-1). As such, the use of such terms here is vague and ambiguous. Further answering, Defendant states that his work at NRP or Lotus focused on d-amphetamine, hydrocodone, oxycodone, and/or certain salts thereof in conjunction with certain of one or more natural standard amino acids. Defendant denies any implication that the above allegation accurately describes NRP's actual business or “business model” or NRP's technology or that NRP's technology is the same or similar to the very different technology which Defendant later independently developed with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP. Defendant

denies the remaining allegations of this paragraph.

26. Throughout his employment with NRP, Mickle, either directly or indirectly (e.g., through scientists whose work he directed), contributed to, had access to and personal knowledge of this proprietary information and know-how, which was essential to NRP's ability to make commercially valuable decisions about which products and which combinations of actives and ligands should be pursued.

ANSWER:

Defendant incorporates his answer to paragraphs 14 and 25, above. Defendant lacks sufficient knowledge or information to admit or deny what was essential to NRP's ability to make such commercially valuable decisions, and therefore denies these allegations. Defendant denies the remaining allegations of this paragraph.

27. Among the employees that worked with and for Mickle at NRP were three scientists: Barney S. Bishop, Ph.D. (NRP Senior Scientist), Sven Guenther, Ph.D. (NRP Research Assistant and Environmental Safety Officer) and Sanjib Bera, Ph.D. (NRP Research Assistant) (hereinafter referred to as "NRP Scientists"). Additionally, Mickle's future wife, then known as Christal Miller ("Mickle's wife"), worked for NRP as a Research Scientist during Mickle's tenure at NRP.

ANSWER:

Defendant admits that among the employees that he worked with or that worked for him were Barney S. Bishop, Ph.D., Sven Guenther, Ph.D., and Sanjib Bera, Ph.D., and that Christal Miller worked for NRP, and sometime after she left NRP, she became Dr. Mickle's wife. Defendant lacks sufficient knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies the same.

28. In connection with the commencement of their employment with NRP, each of the NRP Scientists and Mickle's wife entered into employment contracts that are virtually the same as Mickle's and obligate them to protect and preserve NRP's proprietary information, to convey to NRP all Discoveries, and to use all such information solely for the benefit of NRP.

ANSWER:

Defendant lacks sufficient knowledge or information to admit or deny the allegations of this paragraph, and therefore denies the same.

29. All of these NRP Scientists learned about CarrierwaveTM while working for NRP. Some of the NRP Scientists were directly supervised by Mickle on projects that utilized the CarrierwaveTM technology. Bishop, along with Mickle, was an inventor on the NRP patents described below, which involved the conjugation of amino acids to amphetamine.

ANSWER:

Defendant incorporates by reference his answer to paragraph 12, and Defendant therefore denies the first two sentences of this paragraph. Defendant admits that he and Bishop are listed as inventors on certain patents described below, which claim the conjugation of l-lysine to d-amphetamine or a particular mesylate salt thereof. Defendant denies the remaining allegations of this paragraph.

30. Mickle continued in this key role as Director, which carried with it significant fiduciary duties to NRP, for the remainder of his tenure with NRP, a period of nearly three years.

ANSWER:

Denied.

31. The information described in paragraphs 23 through 26 was confidential and proprietary to NRP and was treated as such by NRP during Mickle's employment, except when NRP made the decision to make certain portions of this information public.

ANSWER:

Defendant incorporates his answers to paragraphs 23 through 26. Defendant admits that some, but not all, information disclosed was or may have been confidential and/or proprietary until such time as it was publicly disclosed. Further answering, Defendant states that he did not have access to or knowledge of all of the information described in paragraphs 23 through 26, and

that the information he did have access to did not involve the very different technology which Defendant later independently developed in connection with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP. Defendant further denies any implication that the development work of Defendant and KemPharm utilized any confidential or proprietary information of Shire or NRP. Defendant lacks sufficient knowledge or information to admit or deny the remainder of the allegations of this paragraph, and therefore denies these allegations.

32. All of the foregoing information relating to the development of prodrugs at NRP whether generated directly by Mickle, the NRP Scientists, Mickle's wife or other NRP employees at the direction of Mickle, was (and is) the exclusive property of NRP. At no time did NRP give the defendants consent to have access to or to use any of its property after Mickle's employment with NRP came to an end in October 2005.

ANSWER:

Denied.

C. Mickle's Drug Development Efforts at NRP Result in Multiple Patents and Patent Applications Applying CarrierwaveTM to Amphetamine

33. During his employment with NRP, Mickle directed and was responsible for the research and development that applied CarrierwaveTM to amphetamine as described in, for example:

Patent / Application No	Filing Date	Exhibit No
7,105,486 ("the '486 patent")	June 1, 2004	8
7,223,735 ("the '735 patent")	June 1, 2004	9
7,375,083 ("the '083 patent")	September 30, 2004	10
7,700,561 ("the '561 patent")	April 10, 2006	11
11/089,056 ("the '056 application")	March 25, 2005	12

ANSWER:

Defendant incorporates his answer to paragraphs 12 and 25, above. Defendant therefore denies the allegations and implications regarding Carrierwave in this paragraph. Defendant admits that he generally directed and was responsible in part for certain research and development at NRP such as reflected in Defendant's answer to paragraph 25, above, and that certain of such work is claimed and/or disclosed in the identified U.S. patents. Defendant denies that he directed and was responsible for all of the work disclosed in the identified U.S. patents and application. Defendant denies the remaining allegations of this paragraph.

34. The '486, '735, '083 and '561 patents and the '056 application, all of which show Mickle as the first named inventor, disclose amphetamine conjugated with "one or more unnatural, non-standard, or synthetic amino acids" Ex. 8, '486 patent at col. 11,11. 48-58; Ex. 9, '735 patent at col. 11,11. 29-39; Ex. 10, '083 patent at col. 17, 1. 59—col. 18,1. 2; Ex. 11, '561 patent at col. 9,11. 1-11; Ex. 12, '056 application at pp. 7-8, ¶ 175. Under Mickle's direction and supervision, at least one employee who reported to him conjugated one or more unnatural, non-standard, or synthetic amino acids to amphetamine.

ANSWER:

Defendant admits that he is the first named inventor listed on the above-identified patents and application, and that they state: "In another embodiment, the amino acid or peptide is comprised of one or more unnatural, non-standard, or synthetic amino acids" Defendant denies that the above-identified patents disclose an amphetamine conjugated with a non-standard amino acid and further answers that the identified patents and application do not provide a written description and/or enable one of skill in the art to make or use an embodiment of any invention involving an amphetamine and a non-standard amino acid. Defendant further denies any implication that the above accurately describes NRP's actual business, "business model,"

patents, patent applications, or that NRP's technology is the same or similar to the very different technology which Defendant later independently developed with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP. Defendant denies the remainder of the allegations of this paragraph.

35. Mickle also directed and was responsible for the research and development that applied Carrierwave™ to hydrocodone. At least one NRP employee, who worked with Mickle, conjugated one or more unnatural, non-standard, or synthetic amino acids to hydrocodone.

ANSWER:

Defendant incorporates by reference his answer to paragraphs 12 and 25, above, and Defendant therefore denies the allegations and implications regarding Carrierwave™ in this paragraph. Defendant admits that he generally directed and was responsible, in part, for certain research and development directed to medicinal chemistry for a hydrocodone prodrug involving hydrocodone and one or more natural standard amino acids, but denies the remainder of the allegations of the first sentence. Defendant lacks sufficient knowledge or information to admit or deny the remainder of the allegations of this paragraph, and therefore denies the same.

36. Also during his employment, Mickle directed and was responsible for the research and development that applied Carrierwave™ to oxycodone. Under Mickle's direction and supervision, at least three NRP employees conjugated one or more unnatural, non-standard, or synthetic amino acids to oxycodone.

ANSWER:

Defendant incorporates by reference his answer to paragraphs 12 and 21, above, and Defendant therefore denies the allegations and implications regarding Carrierwave in this paragraph. Defendant admits that he generally directed and was responsible, in part, for certain research and development of an oxycodone prodrug involving oxycodone and a natural standard

amino acid, but denies the remainder of the allegations of the first sentence. Defendant further admits, based on one or more of the patents or application identified above, that at least one NRP employee, who worked with Dr. Mickle on other matters, may have attempted to conjugate one or more unnatural or synthetic amino acids (namely, homophenylalanine and/or norleucine) to oxycodone, but otherwise denies the allegations of the second sentence. Defendant denies that synthetic amino acids include non-standard amino acids. Defendant lacks sufficient knowledge to admit or deny that at least three NRP employees conjugated one or more unnatural or synthetic amino acids to oxycodone, and therefore denies this allegation. Defendant denies the remainder of the allegations in this paragraph.

37. Consistent with his Employment Agreement, Mickle executed the Assignment Agreements for the patent applications that later became the '486 and '735 patents on October 25, 2004, the '083 patent on December 4, 2004, the '561 patent on August 28, 2006, and the '056 application on April 27, 2005. Ex. 2, Mickle Assignment of U.S. Patent No. 7,105,486; Ex. 3, Mickle Assignment of U.S. Patent No. 7,223,735; Ex. 4, Mickle Assignment of U.S. Patent No. 7,375,083; Ex. 5, Mickle Assignment of U.S. Patent No. 7,700,561; Ex. 6, Mickle Assignment of U.S. Patent Application No. 11/089,056.

ANSWER:

Admitted.

38. The Assignment Agreements provided that Mickle and his co-inventors:

invented certain new and useful improvements in and to the subject matter of [the titled application] described in [that] application; and that Mickle and his co-inventors:

hereby sell, *assign* and transfer unto [New River], *its successors . . . entire right, title and interest in . . . any other United States applications . . . based in whole or in part on said United States application or in whole or in part on said improvements, any foreign applications, including . . . international and regional applications*, based in whole or in part. . . on said improvements, and in and to *any and all letters patent*, including extensions thereof, of any country which have been or may be granted on any of the aforesaid applications or on said improvements or any parts

thereof.

Exs. 2-6 (emphasis added).

ANSWER:

Defendant admits that he executed the aforesaid assignment agreements, but Defendant denies that the above referenced text is complete and denies that it includes such emphases. Further answering, Defendant states that the text of the Assignment documents is set forth therein and speaks for itself.

39. In addition, Shire has filed U.S. Patent Application No. 12/881,008 with the U.S. Patent and Trademark Office. This application is directed to amphetamine conjugated with one or more unnatural, non-standard, or synthetic amino acids. Mickle is a named inventor on this patent application.

ANSWER:

Defendant lacks sufficient knowledge or information to admit or deny the allegations of this paragraph, and therefore denies same. Further answering, Defendant states that U.S. Patent Application No. 12/881,008 is not publicly available, and Plaintiff failed to attach a copy to the Complaint.

D. Mickle Abruptly Resigns from His Employment at NRP and Thereafter Refuses to Work

40. Without warning, on October 11, 2005, Mickle sent a letter to Mr. Krish Krishnan ("Krishnan"), Chief Financial Officer and Chief Operating Officer of NRP, and Ms. Suma Krishnan, Vice President of Product Development of NRP, tendering his resignation effective November 9, 2005. Mickle cited undisclosed "personal reasons" for his departure.

ANSWER:

Defendant denies that his resignation came "without warning," and that his resignation letter tendered his resignation effective November 9, 2005. Defendant further denies that either

the quotation marks or the word “undisclosed” appeared in conjunction with personal reasons in the subject resignation letter. Defendant admits the remainder of this paragraph.

41. The next day, October 12, 2005—despite the effective date stated in his resignation letter in which he would work the thirty (30) day notice period required by his Employment Agreement—Mickle refused to perform work at NRP. In response, given the importance of his position as Director and the need to protect its valuable proprietary and confidential information, NRP terminated Mickle's employment effective immediately.

ANSWER:

Defendant admits that in his resignation letter he agreed to work the thirty (30) day notice period required by his Employment Agreement, but denies the remaining allegations of the first sentence of this paragraph. Further answering, Defendant states that despite his agreement to work the thirty (30) day notice period, on October 12, 2005, NRP terminated his employment effective immediately. Defendant lacks sufficient knowledge or information to admit or deny the allegations in the second sentence of this paragraph, and therefore denies the same.

42. Since NRP allowed Mickle to use his personal laptop computer and work from his home (at that point located in Charlottesville, Virginia), NRP was concerned that Mickle retained confidential and proprietary information regarding NRP following his termination. During an exit interview held on October 15, 2005, Mickle agreed to return company documents and materials promptly.

ANSWER:

Defendant admits that he used his personal laptop computer and worked from his home at certain times and that during an interview held on October 15, 2005, he was asked to and agreed to return company documents and materials, if any, in his possession. Defendant lacks sufficient knowledge or information to admit or deny the remaining allegations in the second sentence of this paragraph, and therefore denies the same.

43. Following numerous subsequent communications regarding, inter alia, Mickle's

claim that certain stock options should be vested, the parties with the assistance of counsel entered into the Settlement Agreement dated June 12, 2006. *See Ex. 7*, Settlement Agreement.

ANSWER:

Defendant denies the allegation that Dr. Mickle's claim was that certain stock options should be vested. Further answering, Defendant states that the Settlement Agreement was entered into by NRP and Dr. Mickle. Defendant admits the remaining allegations of this paragraph.

44. In the Settlement Agreement, Mickle agreed that his obligations to NRP under his Employment Agreement would continue, including his express statement that Sections 4 through 11, 13 and 14 of the Employment Agreement survived termination of his employment. *See Ex. 7*, Settlement Agreement ¶ 5.

ANSWER:

Defendant admits that the Settlement Agreement states, in part, that “This Agreement shall not have any effect upon your continuing obligations to the Company under your Employment Agreements [and] you agree that all of the provisions contained in Sections 4 through 11, 13, and 14 of your Employment Agreement with the Company ... survived the termination of your employment, that all such provisions remain in full force and effect” Defendant further answers that the text of the document speaks for itself, and on that basis, denies the remaining allegations of this paragraph.

45. In the Settlement Agreement, Mickle also acknowledged that by virtue of his former position with NRP, he has knowledge of certain intellectual property developed on behalf of NRP and other important business matters that NRP considers proprietary. *See Ex. 7*, Settlement Agreement ¶ 6.

ANSWER:

Defendant admits that he executed the Settlement Agreement, and that in ¶ 6 thereof it

states the following:

You further acknowledge that by virtue of your former position with the Company you have knowledge of certain intellectual property developed on behalf of New River and other important business matters that New River considers proprietary.

(D.E. 1-7 at ¶ 6.) Defendant further answers that the text of the document speaks for itself, and on that basis, denies the remaining allegations of this paragraph.

46. Shortly after Mickle executed the Settlement Agreement, NRP paid Mickle \$150,000 as consideration for the Settlement Agreement.

ANSWER:

Defendant admits that he executed the Settlement Agreement on June 12, 2006, and that in accordance with the Settlement Agreement, on or about July 21, 2006, NRP paid Dr. Mickle \$150,000 as consideration for his signing the Settlement Agreement.

47. Mickle agreed as part of the Settlement Agreement that if he breached any provision of the Settlement Agreement, which included the incorporated sections of the Employment Agreement, he must repay NRP liquidated damages in the sum of \$149,900. *See Ex. 7, Settlement Agreement ¶ 9.*

ANSWER:

Defendant admits that he executed the Settlement Agreement, and that paragraph 9 thereof states as follows:

You acknowledge that if you violate the confidentiality provisions of this offer or breach any provisions of this Agreement, the Company shall have no obligation to make the settlement payment if not yet given to you and/or that you will be required to repay promptly the settlement amount of \$149,900 if the settlement amount in Section 3 has already been paid to you.

Defendant further answers that the text of the document speaks for itself, and on that basis, denies the remaining allegations of this paragraph.

E. Mickle Starts Competing Pharmaceutical Companies under the "KemPharm" Name

48. On information and belief, less than one (1) month after resigning from NRP and prior to signing the Settlement Agreement (but without the knowledge of or notice to NRP), Mickle formed a business entity, KemPharm, LLC, in Virginia. This entity was a Virginia limited liability company that was chartered on November 8, 2005, and authorized to do business in Virginia. This KemPharm, LLC listed its principal place of business as Mickle's Charlottesville residence. This Virginia entity continued to exist until October 1, 2009, when its charter was cancelled.

ANSWER:

Defendant denies that KemPharm, LLC (Virginia) conducted any business in Virginia. or that it is fairly characterized as a business entity. Defendant lacks sufficient knowledge or information to admit or deny that NRP did not have knowledge that it formed this business entity, and therefore denies the same. Defendant further denies any implication that it operated a business during this time and/or that he violated any provision of any agreement with NRP. Defendant denies any obligation to notify NRP, but admits the remaining allegations of this paragraph.

49. On information and belief, on June 15, 2006, three days after signing the Settlement Agreement with NRP (but without the knowledge of or notice to NRP), Mickle caused a limited liability company by the name of KemPharm, LLC to be formed in Iowa (the "Iowa LLC"). The Iowa LLC listed Mickle's Iowa residence as its principal place of business.

ANSWER:

Defendant admits that KemPharm, LLC was a limited liability company formed in Iowa on June 15, 2006 having Dr. Mickle's residence listed as its principal place of business. Defendant lacks sufficient knowledge or information to admit or deny that NRP did not have knowledge that he formed this business entity, and therefore denies this allegation. Defendant denies any obligation to notify NRP, but admits the remaining allegations of this paragraph. Defendant further denies any implication that he operated a business during this time and/or that

he violated any provision of any agreement with NRP.

50. On October 26, 2006, (but without the knowledge of or notice to NRP) Mickle executed Articles of Incorporation, as the incorporator, for the defendant KemPharm, an Iowa corporation. The Secretary of State of Iowa issued the defendant KemPharm its certificate of incorporation on October 30, 2006, and it became authorized to transact business at that time. Also on October 30, 2006, the Iowa LLC changed its name to Mickle Investments, LLC.

ANSWER:

Defendant lacks sufficient knowledge to admit or deny that NRP did not have knowledge that he formed KemPharm, Inc., and therefore denies this allegation. Defendant states that KemPharm, Inc. was authorized to conduct business in Iowa. Defendant denies any obligation to notify NRP, but admits the remaining allegations of this paragraph as to KemPharm, Inc.

51. The defendant KemPharm describes itself as an early phase biopharmaceutical company that focuses on the discovery of new, safer therapies for ADHD, pain and cardiovascular disease. On information and belief, as further alleged below, each of the entities formed by Mickle that have traded or currently trade under the name of "KemPharm" were formed with this same intent and purpose, which was (and is) to leverage and utilize ideas, information, know-how, discoveries and confidential information learned at NRP, all of which are the exclusive property of NRP, in order to operate a research and development company that would capitalize on such NRP property.

ANSWER:

Defendant admits the first sentence of this paragraph. Defendant admits that KemPharm, Inc. in Iowa was formed with the intent to focus on the discovery of select new, safer therapies for ADHD, pain and cardiovascular disease, but Defendant denies the alleged intent and purpose of KemPharm recited in the second sentence of this allegation and therefore denies the remaining allegations in this paragraph. Further answering, Defendant denies any implication that NRP's technology is the same or similar to the very different technology which Defendant later independently developed with Defendant KemPharm without the use of any confidential or

proprietary information of Shire or NRP. Defendant denies the remainder of the allegations in this paragraph.

52. On information and belief, once the defendant KemPharm was officially incorporated, both KemPharm, LLC, the Virginia limited liability company, and the Iowa LLC/Mickle Investments, LLC conveyed to the defendant KemPharm whatever rights and interests each of them had in any or all research and development engaged in by Mickle and others, including his wife, who was working with him.

ANSWER:

Denied.

53. Mickle is (and at all times has been) the President and Chief Scientific Officer of KemPharm. Mickle's wife, now Christal Mickle, is listed as the Vice President of Corporate Affairs.

ANSWER:

Defendant denies that Dr. Mickle is, and has always been, Chief Scientific Officer.

Defendant admits the remaining allegations of this paragraph.

54. On December 11, 2006, and on February 8, 2007, Mickle filed two provisional patent applications, U.S. Application Nos. 60/869,375 (Exhibit 13) and 60/888,870 (Exhibit 14), respectively, directed to the same conjugates he had responsibility for developing while employed by NRP—namely one or more unnatural, non-standard, or synthetic amino acids conjugated to amphetamine. Like all provisional patent applications, neither of these filings were publically available at the time of filing.

ANSWER:

Defendant admits that he filed two provisional patent applications, U.S. Application Serial Nos. 60/869,375 (Exhibit 13) and 60/888,870 (Exhibit 14) on the dates listed, and that they were not publicly available at the time of filing. Defendant denies the remaining allegations of this paragraph. Defendant further denies any implication that NRP's actual business or "business model" or that NRP's technology is or was the same or similar to the very different

technology which Defendant later independently developed in connection with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP.

55. Shortly thereafter, (i.e., January 29, 2007, and April 5, 2007) without the knowledge or consent of either NRP or Shire, Mickle improperly assigned to the defendant KemPharm his "entire worldwide right, title and interest in and to the invention. . . or improvements of" these two provisional patent applications. Exhibit 15, U.S. Application No. 60/869,375 Assignment; Exhibit 16, U.S. Application No. 60/888,870 Assignment. These assignment agreements also expressly assign KemPharm rights to "any and all other applications [KemPharm] may file. . . on said invention or improvements thereof, and any and all divisions, continuations, continuations-in-part,. . . and any extensions filed in the United States or any Foreign country. . ." Ex. 15; Ex. 16.

ANSWER:

Defendant admits that he assigned these two provisional patent applications to Defendant KemPharm on the dates listed. Defendant states that the above-quoted language from these assignments is incomplete. Defendant admits that the assignments for these applications contain the above-quoted language, but do not contain the ellipses that appear above. Defendant denies that the assignments to KemPharm were improper, and denies the implication that NRP or Shire were required or entitled to have either knowledge of and/or consent to these assignments. Defendant lacks sufficient knowledge or information to admit or deny that NRP did not have knowledge of or consent to these assignments, and therefore denies these allegations. Defendant denies the remaining allegations of this paragraph.

56. At some point, KemPharm began operations in Blacksburg, Virginia, and currently operates a facility located in the Virginia Tech Corporate Research Center in Blacksburg. Although it had been operating in the Commonwealth of Virginia for some time, on December 15, 2009, the defendant KemPharm took the steps necessary to officially become qualified to do business in Virginia and appointed a registered agent.

ANSWER:

Defendant denies KemPharm, Inc. (Iowa) operates, operated, conducted or conducts

business in Virginia. Defendant admits that Defendant KemPharm, Inc. (Iowa) has rented and used a laboratory facility located in the Virginia Tech Corporate Research Center in Blacksburg for a period of time and that on December 15, 2009, KemPharm, Inc. (Iowa) obtained a certificate from the Commonwealth of Virginia authorizing KemPharm Iowa to do business in Virginia and appointed a registered agent. Defendant denies the remaining allegations of this paragraph.

57. Recently, Shire discovered that in the spring of 2007 Travis and Christal Mickle ("the Mickles") aggressively pursued hiring NRP employees and in fact ultimately hired some of them. The Mickles held interviews in Blacksburg, Virginia after inviting employees from the NRP research and development team to consider working for them.

ANSWER:

Defendant states that the term "aggressively" is vague and ambiguous in the context of this allegation. Defendant therefore lacks sufficient knowledge or information to admit or deny this allegation, and therefore denies the same. Defendant admits that in about March 2007, after Shire publicly announced in February 2007 that NRP's Radford headquarters and Blacksburg research and development division was closing and at best a small number of the company's forty-six employees would be retained, and after Shire advised NRP's research and development employees in February 2007 that they would be terminated, Travis and Christal Mickle pursued hiring certain former NRP employees that were or would be terminated, and did hire two former NRP employees in the summer of 2007. Defendant lacks sufficient knowledge or information to admit or deny that Shire recently discovered any of the allegations in this paragraph, and therefore denies this allegation. Defendant denies the remaining allegations in this paragraph.

58. Currently, a number of former NRP employees are employed by KemPharm, including, but not limited to, the Mickles and the NRP Scientists:

- a. Travis Mickle, Ph.D.: President and Chief Scientific Officer of KemPharm (former NRP Director of Drug Discovery and Chemical Development);
- b. Christal Mickle, M.A.: Vice President of Corporate Affairs (former NRP Research Assistant);
- c. Barney S. Bishop, Ph.D.: Chairman of Scientific & Medical Advisory Board at KemPharm (former NRP Senior Scientist);
- d. Sven Guenther, Ph.D.: Vice President of Research at KemPharm (former NRP Research Assistant and Environmental Safety Officer); and
- e. Sanjib Bera, Ph.D.: Group Leader at KemPharm (former NRP Research Assistant).

ANSWER:

Defendant admits that Dr. Mickle is employed by KemPharm, Inc. as its President, that Christal Mickle is employed as Vice President of Corporate Affairs, that Dr. Guenther is employed as Vice President of Research, and that Dr. Bera is employed as Group Leader. Defendant lacks sufficient knowledge and information to admit or deny allegations regarding Barney S. Bishop, Ph.D.'s title at NRP, and therefore denies this allegation. Defendant denies the remainder of the allegations in this paragraph.

59. Under Mickle's direction, and with the assistance of Christal Mickle and the NRP Scientists, KemPharm has implemented a business and development model based on what these individuals learned at NRP. Specifically, KemPharm reports that its business and development model focuses on the improvement of the effectiveness and safety of existing FDA-approved drugs in established, multi-billion dollar markets. Aspects of this business strategy include reduced drug development timelines for drug products with the potential for intellectual property protection.

ANSWER:

Defendant states that Plaintiff misleadingly quotes a portion of a sentence from a KemPharm document in forming the allegations of this paragraph. Further answering, Defendant admits that KemPharm reports that it intends to use KemPharm's proprietary technology to improve the effectiveness and safety of existing FDA-approved drugs in established, multi-billion dollar markets. Further answering, Defendant admits that KemPharm

reports that it believes that entering these drug markets with KemPharm's proprietary technology will provide a clear path to commercially successful products, reduced drug development timeliness and costs and secure intellectual property protection. Defendant denies the remaining allegations of this paragraph.

60. KemPharm created this business and development model utilizing what it describes as a "unique" technology, which it refers to as its ligand activated therapy (LAT) platform technology. On information and belief, LAT forms the basis for KemPharm's research and development activities.

ANSWER:

Defendant states that there is no reference provided as to the source of the quoted term "unique," and that Defendant's response is based on his understanding of the term unique. Defendant denies the allegations of this paragraph as to "platform technology". Defendant states that Plaintiff's allegations omit important portion(s) from the source of the apparently referenced text. Defendant admits that KemPharm has stated that its "drug discovery and development platform is based on [Kempharm's] proprietary Ligand Activated Therapy (LAT) approach." Defendant denies the remaining allegations of this paragraph.

61. However, on information and belief, KemPharm's LAT platform technology is the same as NRP's CarrierwaveTM platform technology. Both CarrierwaveTM and LAT are built upon the same principles:

- a. Select an FDA-approved drug (API);
- b. Add a ligand to the API;
- c. Form a prodrug;
- d. Administer the prodrug to a patient; and
- e. Release the API.

ANSWER:

Denied.

62. Without authorization or consent, Mickle has utilized and continues to utilize ideas, discoveries, know-how and confidential information for the benefit of himself and KemPharm, which he acquired and/or developed, in whole or in part, while employed by NRP. All such material, ideas, information and discoveries are the exclusive property of NRP ("NRP Property").

ANSWER:

Denied.

63. Attempting to leverage and utilize the NRP Property, KemPharm, under Mickle's direction, has focused its efforts on the very same APIs that the Mickles and the NRP Scientists identified while employed at NRP. Moreover, Mickle has sought to couple these APIs to the very same ligand, amino acids, as did NRP while the Mickles and the NRP Scientists worked for NRP.

ANSWER:

Denied.

64. For example, KemPharm has announced that its lead compound is KP106, which KemPharm describes as a new chemical entity ("NCE") composed of the active pharmaceutical compound D-amphetamine and a ligand. Preclinical studies, according to KemPharm, suggest KP106 may have an improved side effect profile and decreased abuse potential. KemPharm reports that KP106 was created using the LAT technology. On information and belief, the ligand used in KP106 is an amino acid.

ANSWER:

Defendant incorporates his answer to paragraph 60, above. Defendant admits that KemPharm has announced that its lead compound is KP106, which KemPharm and the FDA describe as a new chemical entity ("NCE") composed of the active pharmaceutical compound d-amphetamine and a specific polar hydrophilic ligand. Defendant denies that, or the implication that, the ligand in KP106 is a standard amino acid. Defendant admits that preclinical studies, according to KemPharm, suggest KP106 may have an improved side effect profile and decreased abuse potential. Defendant denies that KP106 was the result of "leverage" or use of NRP property. Further answering, Defendant denies any implication that the above paragraph

accurately describes NRP's actual business, "business model," or intellectual property or that NRP's technology is the same or similar to the very different technology which Defendant later independently developed in connection with Defendant KemPharm without the use of any confidential or proprietary information of Shire or NRP. Further answering, Defendant states that the U.S. Patent and Trademark Office ("Patent Office") has awarded KemPharm, Inc. (Iowa) two U.S. patents. (*Id.*) While Plaintiff alleges that these KemPharm patents and applications are "based [] on" Shire's NRP patents (*see* ¶ 68, *infra*), the Patent Office found that the technology of KemPharm's patents and applications was different—indeed, patentably different—by allowing KemPharm's patents to issue over Shire's '486 and '735 patents. Defendant denies the remaining allegations of this paragraph.

65. Another KemPharm prodrug is KP201, which is reportedly a candidate for the treatment of pain; it is composed of hydrocodone combined with a ligand. Preclinical studies, according to KemPharm, suggest that KP201 may have reduced abuse potential compared with currently approved narcotic analgesics. KemPharm reports that KP201 was created using the LAT technology. On information and belief, the ligand used in KP201 is an amino acid.

ANSWER:

Defendant incorporates his answer to the allegations of paragraph 65. Defendant admits that KP201, identified utilizing KemPharm's proprietary ligand activated therapy (LAT), is KemPharm's prodrug candidate for the treatment of acute pain, and is composed of hydrocodone attached to a ligand that does not contain an amino acid or amino acid derivative. Defendant further admits that KemPharm has reported that pre-clinical studies suggest that KP201 may exhibit unique abuse deterrent properties based on its physicochemical and pharmacological characteristics as compared with currently approved narcotic analgesics. Defendant denies the

fourth sentence – “the ligand used in KP201 is an amino acid” – of this paragraph. Defendant denies the remaining allegations of this paragraph.

66. As previously noted, beginning on December 11, 2006, Mickle has filed, as the sole inventor, a series of patent applications. Each of these applications is directed to conjugating amino acids to amphetamine, which is the very same prodrug focus he had when working for NRP. The following patents and applications are related to Mickle's two provisional patent applications, U.S. Application Nos. 60/869,375 (Ex. 13) and 60/888,870 (Ex. 14), and all, on information and belief, have been assigned by Mickle to KemPharm. *See* Exs. 15-16. These patents and patent applications, along with any other related patents or patent applications (*see, e.g., Exhibit 17*) shall be referred to as the "Disputed Patents and Patent Applications":

Application No	Publication No	Publication Date	Title	Patent Number	Patent Issue Date	Assigned to Shire
11/953,668	U.S. 2008/0139653 (<u>Exhibit 18</u>)	6/12/2008	Non-Standard Amino Acid Conjugates of Amphetamine and Processes for Making and Using the Same	7,776,917 (<u>Exhibit 22</u>)	8/17/2010	No
12/028,152	U.S. 2008/0207757 (<u>Exhibit 19</u>)	8/28/2008	Polar Hydrophilic Prodrugs of Amphetamine and Other Stimulants and Processes for Making and Using the Same	7,772,222 (<u>Exhibit 23</u>)	8/10/2010	No
12/473,903	U.S. 2009/0234018 (<u>Exhibit 20</u>)	9/17/2009	Non-Standard Amino Acid Conjugates of Amphetamine and Processes for Making and Using the Same	Prosecution Pending		No
12/477,616	U.S. 2009/0239949 (<u>Exhibit 21</u>)	9/24/2009	Polar Hydrophilic Prodrugs of Amphetamine and Other Stimulants and Processes for Making and Using the Same	Prosecution Pending		No

ANSWER:

Defendant admits that as previously noted, beginning on December 11, 2006, Dr. Mickle has filed, as the sole inventor, a series of patent applications and that the text of these applications speak for themselves. Defendant admits that each of these applications describes polar hydrophilic prodrug conjugates of amphetamine and a non-standard amino acid including, for example, ornithine, homoarginine, citrulline, or homocitrulline. Defendant admits that the above listed patents and application are related by priority to the two above-identified

provisional applications, and that they have been assigned to KemPharm. Defendant denies the remaining allegations of this paragraph.

67. In the later-half of 2008, Shire first became aware of U.S. Application Nos. 11/953,668 and 12/028,152 when they were published and thus became publically available as U.S. Publication Nos. 2008/0139653 (Ex. 18) and 2008/0207757 (Ex. 19). Shortly thereafter, discussions occurred between Mickle and Shire regarding KemPharm and KP106 wherein a potential business relationship was explored. When these discussions proved unsuccessful in the fall of 2009, Shire informed Mickle it would evaluate all of its options.

ANSWER:

Defendant admits that the above-identified patent applications were published as shown by the records of the United States Patent Office. Defendant lacks sufficient knowledge to admit or deny when Shire first became aware of these applications, and therefore denies this allegation. Defendant states that the phrase “shortly thereafter” is vague and ambiguous in the context of this allegation. Defendant therefore lacks sufficient knowledge or information to admit or deny the allegation as to “shortly thereafter,” and on that basis denies the same. Defendant admits the remaining allegations of the second sentence of this paragraph. Defendant admits the third sentence of this paragraph, including Shire’s threat of a lawsuit if Dr. Mickle refused to agree to the terms then proposed by Shire. Defendant denies the remaining allegations of this paragraph.

F. Shire's Evaluation Revealed Mickle's Impermissible Use of Shire's Property

68. Shire's evaluation revealed that the Disputed Patents and Patent Applications are based in whole or in part on the NRP '486, '735, '083 and '561 patents and the '056 application, or in whole or in part on the improvements of said patents. This intellectual property is Shire's property under the Assignment Agreements and the Employment Agreement as successor-in-interest to NRP. *See Exs. 1-6.*

ANSWER:

Denied.

69. KemPharm claims that the research and development carried out by Mickle under these Disputed Patents and Patent Applications generated the prodrug KP106. KemPharm has also touted the speed by which it has been able to accomplish this development work that it claims is covered by intellectual property (i.e., the Disputed Patents and Patent Applications), and which has significant value (i.e., far in excess of \$75,000). KemPharm is actively seeking investors or buyers for the company based in part on the commercial potential of and intellectual property covering KP106.

ANSWER:

Defendant denies that KemPharm has touted the speed by which it has been able to accomplish this development work that it claims is covered by its intellectual property, which is identified in paragraph 66, *supra*. Defendant admits that KemPharm stated that its own independent research and development, carried out without the use of any confidential or proprietary NRP/Shire information, ideas, discoveries, inventions, processes and methods of operation, generated KP106. Defendant admits that KP106 has significant value (i.e., far in excess of \$75,000). Defendant admits that KemPharm is actively seeking investors or buyers for the company based, in part, on the commercial potential of and intellectual property covering KP106. Defendant denies the remaining allegations of this paragraph.

70. KemPharm knew of the existence of Mickle's contracts with Shire, as NRP's successor-in-interest, specifically the Assignment Agreements and his Employment Agreement, and Mickle's continuing obligations thereunder as alleged herein.

ANSWER:

Defendant states that, while employed by KemPharm, he had knowledge of the Assignment Agreements and his Employment Agreement and the terms thereof. Defendant denies the remaining allegations of this paragraph.

71. Despite his obligations under the Assignment Agreements (Exs. 2-6) to assign all patent applications, based in whole or in part, on the NRP patents as discussed above, Mickle has not assigned any of the Disputed Patents and Patent Applications to Shire as NRP's successor-in-interest. On information and belief, Mickle has instead assigned or licensed,

either directly or indirectly, each of the Disputed Patents and Patent Applications to KemPharm for valuable consideration. *See* Exs. 15-16.

ANSWER:

Defendant denies any obligation to assign the Disputed Patents and Patent Applications to Shire. Defendant admits that he has not assigned any of the Disputed Patents and Patent Applications to Shire and has assigned them to KemPharm for valuable consideration. Defendant denies the remaining allegations of this paragraph.

72. Mickle's failure to promptly and fully disclose, and to assign the Disputed Patents and Patent Applications to Shire constitutes a breach of the Assignment Agreements (Exs. 2-6) and Mickle's Employment Agreement (Ex. 1), and wrongful conduct by KemPharm.

ANSWER:

Denied.

73. Mickle's breach of the Assignment Agreements and the Employment Agreement, and KemPharm's complicity in these breaches at this point, has caused and will continue to cause Shire to suffer irreparable harm, as this intellectual property, which is based in whole or part on the earlier Discoveries that are the sole and exclusive property of Shire as NRP's successor-in-interest, is being withheld and is or may be used for unfair competitive purposes to Shire's detriment, and has or will unjustly enrich KemPharm if left unrestrained.

ANSWER:

Denied.

74. While it is not currently possible to assign a specific dollar amount to damage caused by these breaches, as the harm is irreparable, on information and belief, if left unrestrained both Mickle and KemPharm will be unjustly enriched by entering into unauthorized transactions to license or sell Shire's property for an amount that far exceeds \$75,000.

ANSWER:

Denied.

75. Likewise, Mickle's breach of the Employment Agreement also constitutes a breach of the Settlement Agreement, and this breach has caused Shire as NRP's successor-in-interest to suffer damage. The parties agreed that the correct measure of damage for the separate breach of the Settlement Agreement was for Mickle to pay Shire, as NRP's successor, the sum of \$149,900 as liquidated damages.

ANSWER:

Defendant admits that the Settlement Agreement executed by Dr. Mickle and NRP states:

You acknowledge that if you violate the confidentiality provisions of this offer or breach any provisions of this Agreement, the Company shall have no obligation to make the settlement payment if not yet given to you and/or that you will be required to repay promptly the settlement amount of \$149,900 if the settlement amount in Section 3 has already been paid to you.

(D.E. 1-7 at ¶ 9.) Defendant denies the remaining allegations of this paragraph.

**COUNT I — BREACH OF ASSIGNMENT AGREEMENT
OF U.S. PATENT NO. 7,105,486
(MICKLE)**

76. Shire restates the allegations stated in paragraphs 1 through 75 above, as if fully set forth below.

ANSWER:

Defendant hereby incorporates by reference its answers to paragraphs 1 through 75 above, as if fully set forth herein.

77. Mickle entered into this Assignment Agreement of U.S. Patent No. 7,105,486 (Ex. 2), while employed by and working for NRP in Virginia.

ANSWER:

Admitted.

78. Shire is the successor-in-interest to NRP under this Assignment Agreement and has the legal right to enforce its provisions as the Assignee.

ANSWER:

Defendant lacks sufficient knowledge or information to admit or deny this allegation, and therefore denies this allegation.

79. By reason of his actions as stated above, Mickle breached his contractual obligations to Shire pursuant to the Assignment Agreement of U.S. Patent No. 7,105,486 (Ex. 2). Specifically, Mickle has breached his duty to assign to Shire U.S. Patent Application Nos. 11/953,668; 12/028,152; 12/473,903; and 12/477,616 (Exs. 18-21) and U.S. Patent Nos. 7,776,917 and 7,772,222 (Exs. 22-23) as well as any related patents and patent applications ("the Disputed Patents and Patent Applications"), which are based "in whole or in part" on the subject application of the Assignment Agreement of U.S. Patent No. 7,105,486.

ANSWER:

Denied.

80. As a direct result of the breach, Shire has suffered, is suffering and will continue to suffer irreparable injury for which there is or may be no adequate remedy at law unless and until this Court awards appropriate equitable relief, which includes (a) an order rescinding any assignment or license of the Disputed Patents and Patent Applications by Mickle to KemPharm, (b) an order awarding Shire specific performance that compels Mickle and/or KemPharm to assign the Disputed Patents and Patent Applications over to Shire, and (c) an order for injunctive relief that prevents Mickle or KemPharm from taking any action that will infringe upon, impair or limit Shire's ownership of and rights to the intellectual property reflected in the Disputed Patents and Patent Applications.

ANSWER:

Denied.

81. As a direct and consequential result of Mickle's breach of his contractual obligations to Shire under the Assignment Agreement of U.S. Patent No. 7,105,486, Shire has incurred expenses and suffered monetary damages in an amount exceeding \$75,000.

ANSWER:

Denied.

**COUNT II— BREACH OF ASSIGNMENT AGREEMENT
OF U.S. PATENT NO. 7,223,735
(MICKLE)**

82. Shire restates the allegations stated in paragraphs 1 through 75 above, as if fully set forth below.

ANSWER:

Defendant hereby incorporates by reference its answers to paragraphs 1 through 75 above, as if fully set forth herein.

83. Mickle entered into the Assignment Agreement of U.S. Patent No. 7,223,735 (Ex. 3), while employed by and working for NRP in Virginia.

ANSWER:

Admitted.

84. Shire is the successor-in-interest to NRP under this Assignment Agreement and has the legal right to enforce its provisions as the Assignee.

ANSWER:

Defendant lacks sufficient knowledge or information to admit or deny this allegation, and therefore denies this allegation.

85. By reason of his actions as stated above, Mickle breached his contractual obligations to Shire pursuant to the Assignment Agreement of U.S. Patent No. 7,223,735 (Ex. 3). Specifically, Mickle has breached his duty to assign to Shire U.S. Patent Application Nos. 11/953,668; 12/028,152; 12/473,903; and 12/477,616 (Exs. 18-21) and U.S. Patent Nos. 7,776,917 and 7,772,222 (Exs. 22-23) as well as any related patents and patent applications ("the Disputed Patents and Patent Applications"), which are based "in whole or in part" on the subject application of the Assignment Agreement of U.S. Patent No. 7,223,735.

ANSWER:

Denied.

86. As a direct result of the breach, Shire has suffered, is suffering and will continue to suffer irreparable injury for which there is or may be no adequate remedy at law unless and until this Court awards appropriate equitable relief, which includes (a) an order rescinding any assignment or license of the Disputed Patents and Patent Applications by Mickle, directly or indirectly, to KemPharm, (b) an order awarding Shire specific performance that compels Mickle and/or KemPharm to assign the Disputed Patents and Patent Applications over to Shire, and (c) an order for injunctive relief that prevents Mickle or KemPharm from taking any action that will make use of, impair or limit Shire's ownership of and rights to the intellectual property reflected in the Disputed Patents and Patent Applications.

ANSWER:

Denied.

87. As a direct and consequential result of Mickle's breach of his contractual obligations to Shire under the Assignment Agreement of U.S. Patent No. 7,223,735, Shire has incurred expenses and suffered monetary damages in an amount exceeding \$75,000.

ANSWER:

Denied.

**COUNT III — BREACH OF ASSIGNMENT AGREEMENT
OF U.S. PATENT NO. 7,375,083
(MICKLE)**

88. Shire restates the allegations stated in paragraphs 1 through 75 above, as if fully set forth below.

ANSWER:

Defendant hereby incorporates by reference its answers to paragraphs 1 through 75 above, as if fully set forth herein.

89. Mickle entered into this Assignment Agreement of U.S. Patent No. 7,375,083 (Ex. 4), while employed by and working for NRP in Virginia.

ANSWER:

Admitted.

90. Shire is the successor-in-interest to NRP under this Assignment Agreement and has the legal right to enforce its provisions as the Assignee.

ANSWER:

Defendant lacks sufficient knowledge or information to admit or deny this allegation, and therefore denies this allegation.

91. By reason of his actions as stated above, Mickle breached his contractual obligations to Shire pursuant to the Assignment Agreement of U.S. Patent No. 7,375,083 (Ex. 4). Specifically, Mickle has breached his duty to assign to Shire U.S. Patent Application Nos. 11/953,668; 12/028,152; 12/473,903; and 12/477,616 (Exs. 18-21) and U.S. Patent Nos. 7,776,917 and 7,772,222 (Exs. 22-23) as well as any related patents and patent applications ("the Disputed Patents and Patent Applications"), which are based "in whole or in part" on the subject application of the Assignment Agreement of U.S. Patent No. 7,375,083.

ANSWER:

Denied.

92. As a direct result of the breach, Shire has suffered, is suffering and will continue to suffer irreparable injury for which there is or may be no adequate remedy at law unless and until this Court awards appropriate equitable relief, which includes (a) an order rescinding any assignment or license of the Disputed Patents and Patent Applications by Mickle to KemPharm, (b) an order awarding Shire specific performance that compels Mickle and/or KemPharm to assign the Disputed Patents and Patent Applications over to Shire, and (c) an order for injunctive relief that prevents Mickle or KemPharm from taking any action that will infringe upon, impair or limit Shire's ownership of and rights to the intellectual property reflected in the Disputed Patents and Patent Applications.

ANSWER:

Denied.

93. As a direct and consequential result of Mickle's breach of his contractual obligations to Shire under the Assignment Agreement of U.S. Patent No. 7,375,083, Shire has incurred expenses and suffered monetary damages in an amount exceeding \$75,000.

ANSWER:

Denied.

**COUNT IV — BREACH OF ASSIGNMENT AGREEMENT
OF U.S. PATENT NO. 7,700,561
(MICKLE)**

94. Shire restates the allegations stated in paragraphs 1 through 75 above, as if fully set forth below.

ANSWER:

Defendant hereby incorporates by reference its answers to paragraphs 1 through 75 above, as if fully set forth herein.

95. Mickle entered into this Assignment Agreement of U.S. Patent No. 7,700,561 (Ex. 5), while employed by and working for NRP in Virginia.

ANSWER:

Admitted.

96. Shire is the successor-in-interest to NRP under this Assignment Agreement and has the legal right to enforce its provisions as the Assignee.

ANSWER:

Defendant lacks sufficient knowledge or information to admit or deny this allegation, and therefore denies this allegation.

97. By reason of his actions as stated above, Mickle breached his contractual obligations to Shire pursuant to the Assignment Agreement of U.S. Patent No. 7,700,561 (Ex. 5). Specifically, Mickle has breached his duty to assign to Shire U.S. Patent Application Nos. 11/953,668; 12/028,152; 12/473,903; and 12/477,616 (Exs. 18-21) and U.S. Patent Nos. 7,776,917 and 7,772,222 (Exs. 22-23) as well as any related patents and patent applications ("the Disputed Patents and Patent Applications"), which are based "in whole or in part" on the subject application of the Assignment Agreement of U.S. Patent No. 7,700,561.

ANSWER:

Denied.

98. As a direct result of the breach, Shire has suffered, is suffering and will continue to suffer

irreparable injury for which there is or may be no adequate remedy at law unless and until this Court awards appropriate equitable relief, which includes (a) an order rescinding any assignment or license of the Disputed Patents and Patent Applications by Mickle to KemPharm, (b) an order awarding Shire specific performance that compels Mickle and/or KemPharm to assign the Disputed Patents and Patent Applications over to Shire, and (c) an order for injunctive relief that prevents Mickle or KemPharm from taking any action that will infringe upon, impair or limit Shire's ownership of and rights to the intellectual property reflected in the Disputed Patents and Patent Applications.

ANSWER:

Denied.

99. As a direct and consequential result of Mickle's breach of his contractual obligations to Shire under the Assignment Agreement of U.S. Patent No. 7,700,561, Shire has incurred expenses and suffered monetary damages in an amount exceeding \$75,000.

ANSWER:

Denied.

**COUNT V — BREACH OF ASSIGNMENT AGREEMENT
OF U.S. PATENT APPLICATION NO. 11/089,056
(MICKLE)**

100. Shire restates the allegations stated in paragraphs 1 through 75 above, as if fully set forth below.

ANSWER:

Defendant hereby incorporates by reference its answers to paragraphs 1 through 75 above, as if fully set forth herein.

101. Mickle entered into this Assignment Agreement of U.S. Patent Application No. 11/089,056 (Ex. 6), while employed by and working for NRP in Virginia.

ANSWER:

Admitted.

102. Shire is the successor-in-interest to NRP under this Assignment Agreement and has the legal right to enforce its provisions as the Assignee.

ANSWER:

Defendant lacks sufficient knowledge or information to admit or deny this allegation, and therefore denies this allegation.

103. By reason of his actions as stated above, Mickle breached his contractual obligations to Shire pursuant to the Assignment Agreement of U.S. Patent Application No. 11/089,056 (Ex. 6). Specifically, Mickle has breached his duty to assign to Shire U.S. Patent Application Nos. 11/953,668; 12/028,152; 12/473,903; and 12/477,616 (Exs. 18-21) and U.S. Patent Nos. 7,776,917 and 7,772,222 (Exs. 22-23) as well as any related patents and patent applications ("the Disputed Patents and Patent Applications"), which are based "in whole or in part" on the subject application of the Assignment Agreement of U.S. Patent Application No. 11/089,056.

ANSWER:

Denied.

104. As a direct result of the breach, Shire has suffered, is suffering and will continue to suffer irreparable injury for which there is or may be no adequate remedy at law unless and until this Court awards appropriate equitable relief, which includes (a) an order rescinding any assignment or license of the Disputed Patents and Patent Applications by Mickle to KemPharm, (b) an order awarding Shire specific performance that compels Mickle and/or KemPharm to assign the Disputed Patents and Patent Applications over to Shire, and (c) an order for injunctive relief that prevents Mickle or KemPharm from taking any action that will infringe upon, impair or limit Shire's ownership of and rights to the intellectual property reflected in the Disputed Patents and Patent Applications.

ANSWER:

Denied.

105. As a direct and consequential result of Mickle's breach of his contractual obligations to Shire under the Assignment Agreement of U.S. Patent Application No. 11/089,056, Shire has incurred expenses and suffered monetary damages in an amount exceeding \$75,000.

ANSWER:

Denied.

COUNT VI- BREACH OF EMPLOYMENT AGREEMENT
(MICKLE)

106. Shire restates the allegations stated in paragraphs 1 through 75 above, as if fully set forth below.

ANSWER:

Defendant hereby incorporates by reference its answers to paragraphs 1 through 75 above, as if fully set forth herein.

107. Mickle entered into the Employment Agreement (Ex. 1) with NRP on or about March 6, 2001, when he commenced working for NRP in Virginia.

ANSWER:

Denied.

108. Shire is the successor-in-interest to NRP under the Employment Agreement and thereby stepped into NRP's shoes. Shire has the legal right to enforce the Employment Agreement as the "Company" or "Employer."

ANSWER:

Defendant lacks sufficient knowledge or information to admit or deny this allegation, and therefore denies this allegation.

109. The parties specifically contemplated in Section 11 that in addition to all other remedies that might be available, Shire would be entitled to an award of all forms of equitable relief, as monetary relief would be inadequate to compensate Shire for a breach of the provisions that were designed specifically to protect its valuable property and discoveries.

ANSWER:

Defendant admits that paragraph 11 of the executed Employment Agreement states as follows:

11. Enforcement.

Employee understands and agrees that the Company will suffer irreparable harm if Employee breaches any of Employee's obligations under this Agreement, and that monetary damages will be inadequate to compensate the Company for any such violation. Accordingly, Employee agrees that in any event Employee violates or threatens to violate any of the provisions of this Agreement, the Company, in addition to all the remedies which it may have, will be entitled to temporary, preliminary, and permanent injunctions to prevent or to restrain any such actual or threatened violation by Employee, or by any or all of the employees, partners, employers, agents, or other persons, directly or indirectly acting for, or on behalf of, or with Employee. Employee consents to the issuance of such injunctions as being a reasonable measure to protect Company's rights.

(D.E. 1-1 at ¶ 11.) Defendant further answers that the text of the document speaks for itself, and on that basis, denies the remaining allegations of this paragraph.

110. By reason of his actions as stated above, Mickle breached his contractual obligations to Shire pursuant to the Employment Agreement (Ex. 1). Specifically, Mickle has breached Sections 4, 6 and 7 of the Employment Agreement as follows:

- a. Mickle has used and improperly asserted ownership over Shire's property without consent or authorization;
- b. Mickle failed to hold NRP's Confidential Information in trust for the sole benefit of NRP and its successor, Shire; and
- c. Mickle failed to promptly and fully disclose, record and assign all of the Discoveries "which relate to or are useful to" Shire's business that Mickle developed during his employment at NRP.

ANSWER:

Denied.

111. As a direct result of these breaches, Shire has suffered, is suffering and will continue to suffer irreparable injury for which there is or may be no adequate remedy at law unless and until Shire is awarded full and complete equitable relief, including without limitation (a) an order rescinding any assignment or license of the Disputed Patents and Patent Applications by Mickle to KemPharm, (b) an order of specific performance compelling Mickle and/or KemPharm to transfer and assign the Disputed Patents and Patent Applications over to Shire, (c) an order granting injunctive relief that prevents Mickle or KemPharm (and all others acting in concert with them) from taking any action

that will infringe upon, impair or limit Shire's ownership of and its unrestricted rights to any property of any kind that belongs to Shire, including, but not limited to, the intellectual property reflected in the Disputed Patents and Patent Applications, and (d) imposition of a constructive trust and/or such other equitable relief as needed to fully implement the terms of the Employment Agreement.

ANSWER:

Denied.

112. As a direct and consequential result of Mickle's breach of his contractual obligations to Shire under the Employment Agreement, Shire has incurred expenses and suffered monetary damages in an amount exceeding \$75,000.

ANSWER:

Denied.

113. Further, as alleged, Mickle has acted in a manner that has caused Shire to seek judicial relief and to incur expenses, costs and attorney fees in connection therewith. Upon a finding of a breach or a threatened violation of the Employment Agreement and pursuant to Section 13(c) of the Employment Agreement, Shire is entitled to an award of its costs and reasonable attorney fees actually incurred in enforcing the company's rights under the Employment Agreement.

ANSWER:

Denied.

**COUNT VII- TORTIOUS INTERFERENCE WITH CONTRACT
(KEMPHARM)**

114. Shire restates the allegations stated in paragraphs 1 through 113.

ANSWER:

Defendant hereby incorporates by reference its answers to paragraphs 1 through 113 above, as if fully set forth herein.

115. KemPharm had knowledge of the following contracts that existed between Mickle and Shire as NRP's successor-in-interest: the Assignment Agreement of U.S. Patent No.

7,105,486 (Ex. 2), the Assignment Agreement of U.S. Patent No. 7,223,735 (Ex. 3), the Assignment Agreement of U.S. Patent No. 7,375,083 (Ex. 4), the Assignment Agreement of U.S. Patent No. 7,700,561 (Ex. 5), the Assignment Agreement of U.S. Patent Application No. 11/089,056 (Ex. 6), and the Employment Agreement signed on March 6, 2001 (Ex. 1) (collectively "the Mickle Agreements").

ANSWER:

Defendant states that, while employed by KemPharm, he had knowledge of the Assignment Agreements between Dr. Mickle and NRP and his Employment Agreement with Lotus executed on March 6, 2001. Defendant denies the remaining allegations of this paragraph.

116. The Mickle Agreements are valid contracts that create rights which are enforceable by Shire.

ANSWER:

Denied.

117. Despite its knowledge of the existence of these contracts, and the enforceable rights of Shire as well as the continuing obligations they imposed on Mickle, KemPharm wrongfully, and with the intent to cause Mickle to breach his obligations under each of these Agreements, induced him to assign or license the Disputed Patents and Patent Applications and to disclose and use NRP Property in violation of his contractual obligations to Shire. *See Exs. 15-16.*

ANSWER:

Denied.

118. In accepting the rights to these Disputed Patents and Patent Applications and the benefits flowing from the use of the NRP Property, KemPharm knew that Shire's rights under the Mickle Agreements would be violated, and nonetheless wrongfully induced Mickle and wrongfully accepted this valuable property, which belongs to Shire.

ANSWER:

Denied.

119. As alleged above, Mickle did breach the Mickle Agreements and this has caused Shire to suffer and it will continue to suffer irreparable injury for which there is or may be no adequate remedy at law, unless KemPharm is permanently enjoined from continuing to interfere with its rights created by the Mickle Agreements, and is made to account for all ill-gotten gains it may have obtained by selling or attempting to license or sell property that rightfully belongs to Shire.

ANSWER:

Denied.

120. In connection with the breach of these Mickle Agreements, KemPharm has also obtained other NRP property and the benefit of certain know-how that has permitted KemPharm to accelerate its development process far quicker than otherwise would have been possible, even though all of such NRP Property is the exclusive property of Shire.

ANSWER:

Denied.

121. At no time did NRP or its successor Shire give Mickle or KemPharm the right to have access to or to utilize any of the NRP property.

ANSWER:

Denied.

122. KemPharm has damaged Shire by its actions and has been and will continue to be unjustly enriched by its wrongful and tortious interference with Shire's contractual rights under the Mickle Agreements.

ANSWER:

Denied.

123. The damage Shire has suffered as a result of this tortious interference with its contractual rights is real, and is continuing. KemPharm's wrongful acts have caused Shire to suffer and it will continue to suffer irreparable harm for which there is no adequate remedy at law, unless full and complete equitable relief is awarded against KemPharm.

ANSWER:

Denied.

124. Among the forms of equitable relief that is appropriate are the following: (a) an injunction prohibiting KemPharm and all those acting in concert with it from violating or inducing Mickle or any of the NRP Scientists from violating their Employment Agreements; (b) an order of rescission invalidating any assignment or license of the Disputed Patents and Patent Applications to KemPharm, (c) imposition of a constructive trust and/or an order of specific performance or specific restitution that requires KemPharm to transfer or assign any rights it owns or claims to own in the Disputed Patents and Patent Applications to Shire, (d) an order compelling an accounting and imposition of a construction trust of all monies KemPharm has received from third parties in connection with the Disputed Patents and Patent Applications, and requiring KemPharm to pay over any ill-gotten gains obtained from its wrongful acts, and (e) such other equitable relief as may be necessary.

ANSWER:

Denied.

**COUNT VIII- BREACH OF SETTLEMENT AGREEMENT
(MICKLE)**

125. Shire restates the allegations stated in paragraphs 1 through 75, and 106 through 113 above, as if fully set forth below.

ANSWER:

Defendant hereby incorporates by reference its answers to paragraphs 1 through 75 and 106 through 113 above, as if fully set forth herein.

126. The Settlement Agreement (Ex. 7) made by NRP and Mickle on June 12, 2006, was entered into and is subject to the laws of Virginia.

ANSWER:

Admitted.

127. In consideration for Mickle's obligations under the Settlement Agreement, NRP paid Mickle \$150,000.

ANSWER:

Defendant admits that under the Settlement Agreement, NRP paid Dr. Mickle \$150,000 in consideration of Dr. Mickle's execution of the Agreement and to resolve any and all disputes between New River and Dr. Mickle, including NRP's refusal to provide Dr. Mickle with certain stock options under his Incentive Stock Option Agreement.

128. Shire is the successor-in-interest to NRP and has the right to enforce the provisions of the Settlement Agreement as if it were NRP.

ANSWER:

Defendant lacks sufficient knowledge or information to admit or deny this allegation, and therefore denies this allegation.

129. In Section 5 of the Settlement Agreement, Mickle agreed to incorporate by reference Sections 4 through 11, 13 and 14 of the foregoing Employment Agreement as additional terms to the Settlement Agreement.

ANSWER:

Defendant admits that Section 5 of the Settlement Agreement references Sections 4-11, 13 and 14 of the Employment Agreement and further uses the words "those provisions in the future as if those provisions were incorporated into this Agreement." Defendant states that the text of the document speaks for itself and on that basis denies the reminder of this allegation.

130. By reason of his actions as stated above, whereby Mickle breached his Employment Agreement as alleged in paragraphs 106-113 of this Complaint, Mickle has also breached his contractual obligations to Shire under the Settlement Agreement (Ex. 7).

ANSWER:

Denied.

131. Mickle agreed that if he breached this Settlement Agreement by violating the Employment Agreement, that in addition to all remedies Shire may have for the breach of the Employment Agreement, he would pay Shire (as NRP's successor) liquidated damages in the amount of \$149,900.

ANSWER:

Defendant admits that Section 9 of the Settlement Agreement states as follows:

You acknowledge that if you violate the confidentiality provisions of this offer or breach any provisions of this Agreement, the Company shall have no obligation to make the settlement payment if not yet given to you and/or that you will be required to repay promptly the settlement amount of \$149,000 if the settlement amount in Section 3 has already been paid to you.

Defendant further answers that the text of the document speaks for itself, and on that basis, denies the remaining allegations of this paragraph.

132. Further, as alleged, Mickle has acted in a manner that has caused Shire to seek judicial relief and to incur expenses, costs and attorney fees in connection therewith. Pursuant to Section 5 of the Settlement Agreement, which incorporates Section 13(c) of the Employment Agreement, Shire is entitled to an award of its costs and reasonable attorney fees actually incurred in enforcing the company's rights under the Employment Agreement.

ANSWER:

Denied.

* * *

Defendant denies any allegation herein that was not otherwise admitted.

AFFIRMATIVE DEFENSES

Further responding to the Complaint, Defendant Travis C. Mickle, Ph.D. states his affirmative defenses to the Complaint as follows:

FIRST AFFIRMATIVE DEFENSE

133. Plaintiff's Complaint fails to state a cause of action against Defendant Mickle.

SECOND AFFIRMATIVE DEFENSE

134. Plaintiff's claims are barred by the doctrines of unclean hands, estoppel, waiver, acquiescence and/or laches.

THIRD AFFIRMATIVE DEFENSE

135. At least Provisions ¶¶ 4, 6, 7, 10 and 11 of the Employment Agreement (D.E. 1-1) between Dr. Mickle and NPR, are invalid and/or unenforceable non-compete and/or post-termination restraints at least if they are interpreted to restrict the conduct complained of and/or as interpreted by Shire. At least to that extent, the restraints on Dr. Mickle are not reasonable as they are greater than necessary to protect Shire's legitimate business interests, they are unduly harsh and oppressive in curtailing Dr. Mickle's ability to earn a livelihood, and they are not reasonable as a matter of sound public policy.

FOURTH AFFIRMATIVE DEFENSE

136. Provisions of the Settlement Agreement (D.E. 1-7) between Dr. Mickle and NPR, including at least ¶¶ 5 and 9, are invalid and/or unenforceable, including as to non-compete and/or post-termination restraints at least if interpreted to restrict the conduct complained of and/or as interpreted by Shire. At least to that extent, the restraints on Dr. Mickle are not reasonable as they are greater than necessary to protect Shire's legitimate business interests, they are unduly harsh and oppressive in curtailing Dr. Mickle's ability to earn a livelihood, and they are not reasonable as a matter of sound public policy.

FIFTH AFFIRMATIVE DEFENSE

137. At least to the extent the above identified Assignment Agreements of the Shire Patents and Application between Dr. Mickle and NPR could be construed to cover the Disputed

Patents and Patent Applications assigned by Dr. Mickle to Shire, they are invalid and/or unenforceable non-compete and/or post-termination restraints. At least if interpreted to restrict the conduct complained of and/or as interpreted by Shire, they are not reasonable as they are greater than necessary to protect Shire's legitimate business interests, they are unduly harsh and oppressive in curtailing Dr. Mickle's ability to earn a livelihood, and they are not reasonable as a matter of sound public policy.

SIXTH AFFIRMATIVE DEFENSE

138. Enforcement of the subject Employment Agreement, Settlement Agreement and Assignment Agreements, at least if interpreted to restrict the conduct complained of and/or as interpreted by Shire, is unconscionable.

SEVENTH AFFIRMATIVE DEFENSE

139. The subject Employment Agreement, Settlement Agreement and Assignment Agreements or clauses therein are void because there was no meeting of the minds, in that if the Agreements are interpreted in the manner that Shire demands, there was never an agreement.

EIGHTH AFFIRMATIVE DEFENSE

140. Plaintiff Shire lacks standing to enforce the Employment Agreement, Settlement Agreement, and/or Assignment Agreements.

NINTH AFFIRMATIVE DEFENSE

141. Defendant reserves all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the Patent Laws of the United States, and any other defenses, at law or in equity, that may now or in the future be available based on discovery or any other factual investigation concerning this case.

COUNTERCLAIMS

Without waiver of any of its rights, including the right to seek dismissal and/or transfer of this action and KemPharm's right to challenge personal jurisdiction, Travis C. Mickle, Ph.D. ("Dr. Mickle"), by and through his undersigned counsel, and by way of Counterclaims against Shire, LLC ("Shire"), alleges as follows:

NATURE OF THE ACTION

1. This is an action by Defendant and Counter-Claimant Dr. Mickle pursuant to Rule 13 of the Federal Rules of Civil Procedure for declarations of no breach by Dr. Mickle of and the unenforceability of the Employment Agreement, the Settlement Agreement, and the subject provisions of the Assignments, and for breach of the Settlement Agreement by Shire.

PARTIES

2. Dr. Mickle is a citizen of Iowa and is employed by KemPharm, Inc., an Iowa corporation.

3. Upon information and belief, Shire is a Kentucky limited liability company with its principal place of business in Florence, Kentucky. Shire alleges in its Complaint that Shire is the successor-in-interest to New River Pharmaceuticals Inc. ("NRP"), a former Virginia corporation headquartered in Radford, Virginia. Shire also alleges in its Complaint that NRP was known as Lotus Biochemical Corporation ("Lotus").

JURISDICTION AND VENUE

4. This Court has original jurisdiction over this matter pursuant to 28 U.S.C. §§ 1332 and 2201 in that the matter in controversy is between citizens of different states and exceeds the sum or value of \$75,000, exclusive of interest and costs.

5. Shire has consented to personal jurisdiction and venue by commencing its action in this judicial district, as set forth in Shire's Complaint. Shire has also expressly consented to this Court's jurisdiction in the Employment Agreement, which states that "the exclusive jurisdiction for any lawsuit brought to enforce any right[s] or obligations arising under this agreement shall be. . . the United States District Court for the Western District of Virginia." (D.E. 1 at ¶ 13(a).) Shire has reaffirmed its consent to jurisdiction in this Court when it entered into the Settlement Agreement. (D.E. 7 at ¶ 5.)

**BACKGROUND FACTS RELATING TO
DR. MICKLE, NRP/SHIRE, AND KEMPHARM**

A. Dr. Mickle's Employment with NRP

6. On March 5, 2001, Dr. Travis C. Mickle began working for Lotus Biochemical Corporation ("Lotus").

7. On March 6, 2001, Dr. Mickle and Lotus entered into an Employment Agreement (D.E. 1-1.) regarding Dr. Mickle's employment by Lotus.

8. On October 11, 2005, Dr. Mickle submitted his letter of resignation, which provided thirty days notice, to NRP's Krishna Krishan and Suma Krishan.

9. On October 12, 2005, without warning, NRP terminated Dr. Mickle's employment.

10. Dr. Mickle is named as a co-inventor of patents and an application, which he assigned to NRP and/or Shire, including:

- a. U.S. Patent No. 7,105,486 ("the '486 patent");
- b. U.S. Patent No. 7,223,735 ("the '735 patent");
- c. U.S. Patent No. 7,375,083 ("the '083 patent");

- d. U.S. Patent No. 7,700,561 ("the '561 patent"); and
- e. U.S. Application Serial No. 11/089,056 ("the '056 application").

(Hereinafter, collectively, the “Shire Patents and Application.”)

11. The specifications of the Shire Patents and Application do not disclose the following:

- a. homoarginine by name;
- b. citrulline by name;
- c. homocitrulline by name;
- d. l-ornithine-d-amphetamine conjugate;
- e. l-homoarginine-d-amphetamine conjugate;
- f. any prophetic or working examples of conjugates of any amphetamine and one or more non-standard amino acids;
- g. any prophetic or working examples of conjugates of any amphetamine and one or more synthetic amino acids;
- h. any prophetic or working examples of conjugates of any amphetamine and one or more ornithine amino acids;
- i. any prophetic or working examples of conjugates of any amphetamine and one or more homoarginine amino acids;
- j. any prophetic or working examples of conjugates of any amphetamine and one or more citrulline or homocitrulline amino acids;
- k. any prophetic or working examples of conjugates of any hydrocodone and one or more non-standard amino acids;
- l. any prophetic or working examples of conjugates of any hydrocodone and one or more synthetic amino acids; or
- m. any prophetic or working examples of conjugates of any oxycodone and one or more non-standard amino acids.

12. Norluecine is a synthetic amino acid, and is not in fact a non-standard amino acid. Homophenylalanine is a synthetic amino acid, and is not in fact a non-standard amino acid.

13. The specifications of the Shire Patents and Application do not enable a person of ordinary skill in the art to make an amphetamine-non-standard amino acid conjugate, including with ornithine, homoarginine, citrulline, and/or homocitrulline.

14. During Dr. Mickle's employment at Lotus and NRP, Dr. Mickle did not conjugate amphetamine with one or more non-standard amino acids. During this time, none of the scientists supervised by Dr. Mickle conjugated amphetamine with one or more non-standard amino acids. On information and belief, nor did any one else employed at Lotus or NRP conjugate amphetamine with one or more non-standard amino acids during Dr. Mickle's employment with NRP.

15. During Dr. Mickle's employment at Lotus and NRP, Dr. Mickle did not conjugate amphetamine, hydrocodone, or oxycodone with ornithine. During this time, none of the scientists supervised by Dr. Mickle conjugated amphetamine with ornithine. On information and belief, nor did any one else employed at Lotus or NRP conjugated amphetamine, hydrocodone, or oxycodone with ornithine during Dr. Mickle's employment with NRP.

16. During Dr. Mickle's employment at Lotus and NRP, Dr. Mickle did not conjugate amphetamine, hydrocodone, or oxycodone with homoarginine. During this time, none of the scientists supervised by Dr. Mickle conjugated amphetamine with homoarginine. On information and belief, nor did any one else employed at Lotus or NRP conjugate amphetamine, hydrocodone, or oxycodone with homoarginine during Dr. Mickle's employment with NRP.

17. During Dr. Mickle's employment at Lotus and NRP, Dr. Mickle did not conjugate amphetamine, hydrocodone, or oxycodone with citrulline or homocitrulline. During this time,

none of the scientists supervised by Dr. Mickle conjugated amphetamine with citrulline or homocitrulline. On information and belief, nor did any one else employed at Lotus or NRP conjugate amphetamine, hydrocodone, or oxycodone with citrulline or homocitrulline during Dr. Mickle's employment.

18. NRP did not inform Dr. Mickle at any time that one or more NRP scientists conjugated amphetamine with one or more what is in fact non-standard amino acids. NRP also did not inform Dr. Mickle at any time that one or more NRP scientists conjugated hydrocodone with one or more what is in fact non-standard amino acids. Nor did NRP inform Dr. Mickle at any time that one or more NRP scientists conjugated oxycodone with what is in fact one or more non-standard amino acids.

19. NRP did not inform Dr. Mickle that one or more NRP scientists conjugated amphetamine with ornithine, homoarginine, citrulline or homocitrulline at any time.

20. NRP did not inform Dr. Mickle at any time that one or more NRP scientists conjugated hydrocodone and/or oxycodone with ornithine, homoarginine, citrulline or homocitrulline.

21. During Dr. Mickle's employment at NRP and until at least June 13, 2006, NRP did not disclose any "Confidential Information" (as defined in ¶ 6 of the Employment Agreement) or other information to Dr. Mickle describing the manner of making a prodrug comprising what is in fact a non-standard amino acid ligand conjugated with an amphetamine.

22. During Dr. Mickle's employment at NRP and until at least June 13, 2006, NRP did not disclose any "Confidential Information" (as defined in ¶ 6 of the Employment Agreement) or other information to Dr. Mickle describing the manner of making a polar

hydrophilic prodrug comprising an ornithine, homoarginine, citrulline or homocitrulline ligand conjugated with an amphetamine.

B. History of Prodrugs and Vyvanse and Differences Between the Mickle and NRP/Shire Technologies

23. Prodrugs involving conjugates of amphetamine as the API were disclosed in the art at least in the 1970s, long before Dr. Mickle began working for Lotus on March 5, 2001. Prodrugs involving standard amino acid were also disclosed in the art prior to March 5, 2001. To date, there are no marketed prodrugs involving non-standard amino acids. On information and belief, there are no examples of prodrugs comprising ornithine or homoarginine disclosed in the art to December 11, 2006.

24. Shire's Vyvanse is lisdexamfetamine dimesylate, a prodrug of a mesylate salt of d-amphetamine conjugated to l-lysine, a natural standard amino acid. Vyvanse is marketed by Shire to treat ADHD symptoms. During its development, including during pre-clinical and clinical trials, Vyvanse was known as NRP104.

Differences Between Shire Patents and Applications and the Disputed Patents and Applications

Standard v. Non-standard Amino Acids

25. In comparison to conjugates of non-standard amino acids and amphetamine (or opioids), conjugates of standard amino acid and amphetamine (or opioids) are structurally different; pharmacologically different; and exhibit different pharmacokinetic, release, side effect, and safety profiles.

26. In comparison to conjugates of non-standard amino acids and amphetamine (or opioids), conjugates of standard amino acid and amphetamine (or opioids) exhibit different concentration maximum ("C_{max}"), time after administration of a drug when the maximum

plasma concentration is reached (“Tmax”), and therapeutically bioequivalent area under the curve (“AUC”).

27. In comparison to conjugation of standard amino acids to an active pharmaceutical ingredient (“API”), conjugation of non-standard amino acids to an API involves significant experimentation due to the selection of base, co-base, coupling agent/reagent, deprotection agent/reagent, solvent, and/or other agents, reagents, or additives.

Not Pharmaceutical Equivalents

28. For drug products to be pharmaceutically equivalent, the FDA requires at least these criteria:

- a. the two or more drug products contain the same active ingredient(s);
- b. the two or more drug products are of the same dosage form and route of administration; and
- c. the two or more drug products are identical in strength or concentration.

29. Standard amino acid conjugates and non-standard amino acid conjugates are not pharmaceutical equivalents according to the FDA’s definition of “pharmaceutical equivalent.”

30. L-lysine-d-amphetamine (e.g., Vyvanse) and l-ornithine-d-amphetamine are not pharmaceutical equivalents according to the FDA’s definition of “pharmaceutical equivalent.”

31. L-lysine-d-amphetamine (e.g., Vyvanse) and l-homoarginine-d-amphetamine are not pharmaceutical equivalents according to the FDA’s definition of “pharmaceutical equivalent.”

32. L-lysine-d-amphetamine (e.g., Vyvanse) and l-citrulline-d-amphetamine are not pharmaceutical equivalents according to the FDA’s definition of “pharmaceutical equivalent.”

33. L-lysine-d-amphetamine (e.g., Vyvanse) and l-homocitrulline-d-amphetamine are not pharmaceutical equivalents according to the FDA's definition of "pharmaceutical equivalent."

Not Bioequivalents

34. The FDA defines bioequivalent drug products as at least pharmaceutical equivalents that display comparable bioavailability when studied under similar experimental conditions.

35. Standard amino acid conjugates and non-standard amino acid conjugates are not bioequivalents per the FDA's definition of "bioequivalents."

36. L-lysine-d-amphetamine (Vyvanse) and l-ornithine-d-amphetamine are not bioequivalents per the FDA's definition of "bioequivalents."

37. L-lysine-d-amphetamine (Vyvanse) and l-homoarginine-d-amphetamine are not bioequivalents per the FDA's definition of "bioequivalents."

38. L-lysine-d-amphetamine (Vyvanse) and l-homocitrulline-d-amphetamine are not bioequivalents per the FDA's definition of "bioequivalents."

39. L-lysine-d-amphetamine (Vyvanse) and l-citrulline-d-amphetamine are not bioequivalents per the FDA's definition of "bioequivalents."

C. The Mickle Patents and Applications

34. Dr. Mickle is listed as sole inventor on United States Application Serial No. 11/953,668 ("the '668 application"), entitled "Non-standard amino acid conjugates of amphetamine and processes for making and using the same" filed with the United States Patent and Trademark Office on December 10, 2007. The '668 application was allowed on April 7, 2010 and issued on August 17, 2010 as United States Patent No. 7,776,917 ("the '917 patent").

35. Dr. Travis Mickle assigned his rights and interests in the '917 patent and the '668 application to KemPharm, Inc. on January 29, 2007 by virtue of his assignment of United States Patent Application Serial No. 60/869,375 ("the '375 application") to KemPharm, Inc. on that date.

36. Dr. Travis Mickle is listed as sole inventor on United States Application Serial No. 12/028,152 ("the '152 application"), entitled "Polar hydrophilic prodrugs of amphetamine and other stimulants and processes for making and using the same" filed with the United States Patent and Trademark Office on February 8, 2008. The '152 application was allowed on April 12, 2010 and issued August 10, 2010 as United States Patent No. 7,772,222 ("the '222 patent").

37. Dr. Travis Mickle assigned his rights and interests in the '222 patent and the '152 application to KemPharm, Inc. on April 5, 2007 by virtue of his assignment of United States Patent Application Serial No. 60/888,870 ("the '870 application") to KemPharm, Inc. on that date.

38. Dr. Mickle did not conceive of the inventions disclosed and claimed in the '375, '668, '870 and '152 applications and the '917 and '222 patents during his employment with Lotus or NRP. Dr. Mickle conceived and reduced to practice the inventions disclosed and claimed in the '375, '668, '870 and '152 applications and the '917 and '222 patents sometime after October 13, 2006.

39. The claims of the '917 and '222 patents issued over the following patents and published applications assigned to Shire: United States Patent No. 7,105,486 ("the '486 patent"); United States Patent No. 7,223,735 ("the '735 patent"); United States Published Application Serial No. 2005/0038121, which issued as the '735 patent; and United States Published Application Serial No. 2005/0054561, which issued as the '486 patent.

40. By allowing and issuing the claims of the '917 and '222 patents over Shire's '486 and '735 patents, the United States Patent and Trademark Office found that the claims of the '917 and '222 patents are novel and not obvious to a person of ordinary skill in the art in view of Shire's '486 and '735 patents.

COUNTERCLAIM I

(DECLARATORY JUDGMENT THAT DR. MICKLE DID NOT BREACH THE EMPLOYMENT AGREEMENT OR THE SETTLEMENT AGREEMENT)

41. Counterclaimant Dr. Mickle restates the allegations stated in paragraphs 1 through 40 as if fully set forth herein.

42. When Dr. Mickle began his employment with Lotus/NRP, the company provided him with stock options, the terms of which did not require vesting in order to be owned by Dr. Mickle upon termination of his employment. In his resignation letter, Dr. Mickle requested that NRP provide the remaining one-third of his stock options. NRP refused Dr. Mickle's request.

43. Sometime after NPR refused Dr. Mickle's request, an attorney representing Dr. Mickle began negotiating with NRP to obtain Dr. Mickle's stock options. Throughout the negotiations, NRP refused to provide Dr. Mickle with his stock options. NRP ultimately offered to pay Dr. Mickle the sum of \$150,000 to settle this dispute.

44. On June 12, 2006, Dr. Mickle and NRP executed a Settlement Agreement in settlement of the stock option dispute.

45. In its Complaint filed in this action, Shire alleges that Dr. Mickle has breached ¶ 5 of the Settlement Agreement (*see* Complaint, D. E. 1 at ¶ 130). Shire has not alleged that Dr. Mickle violated any other provisions of the Settlement Agreement.

46. Paragraph 5 of the Settlement Agreement states as follows:

This Agreement shall not have any effect upon your continuing obligations to the Company under your Employment Agreement. Specifically, you agree that all of the provisions contained in Sections 4 through 11, 13 and 14 of your Employment Agreement with the Company dated March 6, 2001 (the "Employment Agreement") survived the termination of your employment, that all such provisions remain in full force and effect, and that the Company has the right to expect full compliance with, and to enforce, those provisions in the future as if those provisions were incorporated into this Agreement; provided, however, in the event of any conflict between the provisions of Sections 4 through 11, 13, and 14 of the Employment Agreement conflict with any of the provisions of this Agreement, the provisions of this Agreement shall control.

(D. E. 1-7 at ¶ 5.)

47. Plaintiff alleges that Dr. Mickle breached ¶ 5 of the Settlement Agreement by his alleged breach of ¶¶ 4, 6 and 7 of the Employment Agreement. (D. E. 1 at ¶ 130.)

48. Dr. Mickle denies that he breached ¶¶ 4, 6 and 7 or any other provision of the Employment Agreement.

49. Dr. Mickle also denies that he breached the Settlement Agreement.

50. An actual controversy therefore exists, and a judicial declaration that Dr. Mickle did not breach the Employment Agreement or the Settlement Agreement is necessary and appropriate at this time so that Dr. Mickle can ascertain his rights and duties with respect to the Settlement Agreement and the Employment Agreement.

51. Because Shire has initiated judicial proceedings and Dr. Mickle did not breach the Employment Agreement, Dr. Mickle is entitled to equitable relief, expenses, costs and attorney fees pursuant to at least ¶ 12 of the Settlement Agreement, ¶ 13(c) of the Employment Agreement.

COUNTERCLAIM II

**(DECLARATORY JUDGMENT THAT THE SETTLEMENT
AND EMPLOYMENT AGREEMENTS ARE NOT ENFORCEABLE
AT LEAST IF INTERPRETED IN A WAY THAT RESULTS
IN DR. MICKLE HAVING BREACHED THOSE PROVISIONS AND/OR
THAT SUCH ENFORCEMENT THEREOF IS UNCONSCIONABLE)**

52. Defendant Dr. Mickle restates the allegations stated in paragraphs 1 through 51 as if fully set forth herein.

53. At least ¶¶ 4, 6, 7, 10 and 11 of the Employment Agreement (D.E. 1-1) between Dr. Mickle and NPR are invalid and/or unenforceable non-compete and/or post-termination restraints and enforcement thereof is unconscionable at least as those provisions are interpreted by Shire and/or and to the extent interpreted in a way that results in Dr. Mickle having breached those provisions. At least to that extent, the restraints on Dr. Mickle are not reasonable as they are greater than necessary to protect Shire's legitimate business interests, they are unduly harsh and oppressive in curtailing Dr. Mickle's ability to earn a livelihood, and they are not reasonable as a matter of sound public policy.

54. Because ¶¶ 4, 6 and 7 of the Employment Agreement are unenforceable, ¶ 5 of the Settlement Agreement is also unenforceable.

55. On information and belief, Shire contends that the provisions of the Employment Agreement and Settlement Agreement are enforceable by virtue of the filing of its Complaint herein.

56. An actual controversy therefore exists involving the enforceability of the Employment Agreement and the Settlement Agreement, and a judicial declaration that the at least ¶¶ 4, 6 and 7 of the Employment Agreement and ¶ 5 of the Settlement Agreement are

unenforceable is necessary and appropriate at this time so that Dr. Mickle can ascertain his rights and duties with respect to the Settlement Agreement and the Employment Agreement.

57. Because Shire has initiated judicial proceedings and Dr. Mickle did not breach the Employment Agreement, Dr. Mickle is entitled to equitable relief, expenses, costs and attorney fees pursuant to at least ¶ 12 of the Settlement Agreement, ¶ 13(c) of the Employment Agreement.

COUNTERCLAIM III

(DECLARATORY JUDGMENT THAT DR. MICKLE DID NOT BREACH THE ASSIGNMENT AGREEMENTS OF THE SHIRE PATENTS AND APPLICATION)

58. Dr. Mickle restates the allegations stated in paragraphs 1 through 57 as if fully set forth herein.

59. Shire has filed its Complaint in this action alleging that Dr. Mickle breached Assignment Agreements concerning the '486, '735, '083, and '561 patents and the '056 application, copies found at D.E. 1 – 1-5.

60. Dr. Mickle denies that he breached the Assignment Agreements of the Shire Patents and Application.

61. An actual controversy therefore exists involving whether Dr. Mickle breached the Assignment Agreements, and a judicial declaration that Dr. Mickle did not breach the Assignment Agreements is necessary and appropriate at this time so that Dr. Mickle can ascertain his rights and duties with respect to the same.

COUNTERCLAIM IV

(DECLARATORY JUDGMENT THAT THE ASSIGNMENT AGREEMENTS OF THE SHIRE PATENTS AND APPLICATION ARE NOT ENFORCEABLE AT LEAST IF INTERPRETED IN A WAY THAT RESULTS IN DR. MICKLE HAVING BREACHED THOSE AGREEMENTS AND/OR THAT SUCH ENFORCEMENT THEREOF IS UNCONSCIONABLE)

62. Counter-claimant Dr. Mickle restates the allegations stated in paragraphs 1 through 61 as if fully set forth herein.

63. On information and belief, Shire contends that ¶¶ 4, 6 and 7 of the Assignment Agreements are enforceable by virtue of the filing of its Complaint herein asserting breach of the Assignment Agreements.

64. At least to the extent the above identified Assignment Agreements of the Shire Patents and Application between Dr. Mickle and NPR could be construed to impose a duty on Dr. Mickle to assign the Disputed Patents and Patent Applications to Shire, they are invalid and/or unenforceable non-compete and/or post-termination restraints and enforcement thereof is unconscionable. At least to that extent, the restraints on Dr. Mickle are not reasonable as they are greater than necessary to protect Shire's legitimate business interests, they are unduly harsh and oppressive in curtailing Dr. Mickle's ability to earn a livelihood, and they are not reasonable as a matter of sound public policy.

65. An actual controversy therefore exists involving the enforceability of the Assignment Agreements, and a judicial declaration that the Assignment Agreements are unenforceable is necessary and appropriate at this time so that Dr. Mickle can ascertain his rights and duties with respect to the same.

COUNTERCLAIM V

(PLAINTIFF SHIRE'S BREACH OF THE SETTLEMENT AGREEMENT)

66. Counterclaimant Dr. Mickle restates the allegations stated in paragraphs 1 through 65 as if fully set forth herein.

67. Dr. Mickle and NRP entered into the Settlement Agreement on June 12, 2006.
(D. E. 1-7.)

68. Shire has alleged that it is the successor-in-interest to NRP and on at least that basis has a duty to comply with the provisions of the Settlement Agreement as if it were NRP.
(D. E. 1 at ¶ 128.)

69. Paragraph 8 of the Settlement Agreement states as follows:

You agree that you will refrain from making any comments that are, or are intended to be, detrimental, injurious or derogatory to the interests of New River or any of its affiliates, or to the business or personal reputations of any of their current or former directors, officers, or employees. Similarly, the members of senior management of New River shall refrain from making disparaging, demeaning or derogatory remarks that are intended to injure your business or personal reputation, and members of senior management shall refrain from directing or encouraging others to do the same. Nothing in this paragraph or in this Agreement shall be interpreted or applied to require any party to be untruthful or misleading when responding to any question, inquiry or request for information that is required to be provided by legal process.

(D. E. 1-7 at ¶ 8 (emphasis added).)

70. Paragraph 8 of the Settlement Agreement imposes a duty upon members of senior management of New River and Shire to refrain from making disparaging, demeaning or derogatory remarks that are intended to injure Dr. Mickle's business or personal reputation.

71. Paragraph 2 of the Settlement Agreement states as follows:

The terms and conditions of this Agreement are strictly confidential. . . . The Company will keep this confidential as well, except that the Company may disclose information about this Agreement as may be necessary to comply with reporting or disclosure requirements that apply to publicly traded companies or as

may be determined otherwise necessary or appropriate for a proper corporate purpose.

(D. E. 1-7 at ¶ 2).

72. Mr. Michael Cola is the President of Shire Specialty Pharmaceuticals and is a member of senior management at Shire.

73. On March 9, 2010, Mr. Michael Cola publicly stated at the Cowen and Company Healthcare Conference in Boston, Massachusetts:

Sure. For those of you don't know, KemPharm is led by an ex-New River person. His name is on the intellectual property associated with VYVANSE. I'll tell you – how we feel at Shire, that intellectual property associated with his Phase I study is something we own. It's based on the IP that we acquired, when we acquired New River Pharmaceuticals. And we've had numerous talks with them. I think they understand the situation and they continue to go forward, but at the end of the day, when you see that product, think of it as Shire's intellectual property.

(http://www.corporate-ir.net/ireye/confLobby.zhtml?ticker=SHP.L&item_id=2755342 (webcast)

(hereinafter the “Statement”).)

74. Dr. Mickle is the “ex-New River person” referred to by Mr. Cola in his Statement.

75. Dr. Mickle is the referenced person whose “name is on the intellectual property associated with VYVANSE” and the person referenced in Mr. Michael Cola's statement: “[h]is name is on the intellectual property associated with VYVANSE ... that intellectual property associated with his Phase I study is something we own. It's based on the IP that we acquired, when we acquired New River Pharmaceuticals. And we've had numerous talks with them. I think they understand the situation and they continue to go forward, but at the end of the day, when you see that product, think of it as Shire's intellectual property.”

76. Mr. Cola made this Statement in response to a question posed by a member of the audience who had previously entered into, on behalf of his employer, a contract with KemPharm, Inc. (“KemPharm”) regarding intellectual property that covers KemPharm's KP106.

77. The product referenced in Mr. Cola's statement as undergoing "his Phase I study" is KP106. KP106 is a novel prodrug owned by KemPharm for the treatment of attention-deficit hyperactivity disorder (ADHD). KP106, designated as a new chemical entity ("NCE") by KemPharm and by the FDA, is composed of the active pharmaceutical d-amphetamine and a non-standard amino acid ligand and was created through application of KemPharm's proprietary technology. The KP106 technology is covered by patents and applications, which name Dr. Mickle as the sole inventor and which Dr. Mickle assigned to KemPharm. KP106 is the only KemPharm product that has achieved the Phase I trial stage before the FDA.

78. KP106, the KP106 technology, and the intellectual property that covers KP106 are not Shire's intellectual property.

79. On information and belief, Mr. Cola's Statement comprises remarks intended to injure Dr. Mickle's business and personal reputation.

80. Mr. Cola's Statement is disparaging, demeaning and/or derogatory and, on information and belief, made with the intent to injure Dr. Mickle's personal and business reputation. The Statement implicitly involves allegations that Dr. Mickle stole, misappropriated, filed patent applications on, conducted FDA testing on and/or otherwise acted improperly in claiming ownership of, using, and refusing to return intellectual property to Shire.

81. Shire has acted in a manner that has caused Dr. Mickle to seek judicial relief and to incur expenses, costs and attorney fees in connection therewith. Pursuant to at least ¶ 12 of the Settlement Agreement, ¶ 13 of the Employment Agreement governs any dispute that arises under the Settlement Agreement, and ¶ 13(c) of the Employment Agreement entitles Dr. Mickle to an award of his expenses, costs and attorney fees incurred in enforcing his rights in this claim.

82. Shire's use and public disclosure of the Settlement Agreement by suing Dr. Mickle, is not a proper corporate purpose for disclosure of the agreement.

83. Shire's statement, and possible other statements as yet unknown made to analysts and/or investors, have damaged Dr. Mickle's reputation and/or business interests, including by inhibiting his ability to raise capital to fund the completion of KemPharm's work to bring a new drug product to market.

COUNTERCLAIM VI

(SLANDER)

84. Counterclaimant Dr. Mickle restates the allegations stated in paragraphs 1 through 83 as if fully set forth herein.

85. From at least October 2008 until September 2009, Shire explored the possibility of entering into a business relationship with KemPharm. Under a confidentiality agreement with KemPharm, KemPharm disclosed to Shire the composition of KP106.

86. Mr. Cola either knew, when the statement was made, that it was false, and/or made the statement in reckless disregard for its truth or falsity and without conducting an investigation into whether in fact, Shire had any intellectual property or other claim covering KP106.

87. The Statement was defamatory, as it discredited Dr. Mickle and Dr. Mickle's business in at least the pharmaceutical industry and the investment community for pharmaceutical start-up companies.

88. A reasonable opportunity for further investigation or discovery is likely to show that, agents of Plaintiff have made other defamatory statements about Dr. Mickle and/or his business in at least the pharmaceutical industry and investment community.

89. The Statement, and any other statements that a reasonable opportunity for discovery shows were made, have caused economic and non-economic damage to Dr. Mickle, including to Dr. Mickle's professional business reputation, his ability to raise capital or enter into professional and/or business arrangements, and/or because it deters or inhibits third persons from associating or dealing with him.

PRAYER FOR RELIEF

Dr. Mickle respectfully prays for the following relief:

- A. That Plaintiff take nothing by its Complaint;
- B. That the Court dismiss each and every claim related to Dr. Mickle in Plaintiff's Complaint with prejudice;
- C. That the Court find and enter a judgment declaring that Dr. Mickle did not breach the Employment Agreement, Settlement Agreement, or the Assignment Agreements;
- D. That the Court find and enter a judgment declaring that at least ¶¶ 4, 6, and 7 of the Employment Agreement, ¶ 5 of the Settlement Agreement, and the Assignment Agreements are unenforceable at least if interpreted in a way that results in Dr. Mickle having breached those provisions and/or that such enforcement thereof is unconscionable;
- E. That the Court find and enter a judgment declaring that Plaintiff breached at least ¶¶ 2 and 8 of the Settlement Agreement;
- F. That the Court find and enter a judgment that Plaintiff slandered Dr. Mickle and award economic, non-economic, and punitive damages for Plaintiff's defamatory statements;
- G. That the Court award expenses, costs, and attorney fees to Dr. Mickle; and
- H. That the Court award Dr. Mickle any other relief that the Court may deem just, equitable and proper.

JURY TRIAL DEMAND

Defendant/Counter-claimant Dr. Mickle hereby demands a trial by jury as to all issues so triable herein.

Date: November 12, 2010

Respectfully submitted,

/s/ John E. Davidson
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CERTIFICATE OF SERVICE

I certify that on this 12th day of November, 2010, I electronically filed the foregoing using the Court's CM/ECF system, which will send notification of the foregoing filing to W. David Paxton, Esq., counsel for Plaintiff, Gentry Locke Rakes & Moore, 800 SunTrust Plaza, Roanoke, Virginia 24022-0013.

/s/ John E. Davidson

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